IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MICHAEL BAVARO, derivatively on behalf of VANDA PHARMACEUTICALS, INC., Plaintiff, v. MIHAEL H. POLYMEROPOULOS, M.D., JAMES KELLY, GIAN PIERO REVERBERI, H. THOMAS WATKINS, MICHAEL F. COLA, RICHARD W. DUGAN, VINCENT J. MILANO, and KENNETH BATE, Defendants, and VANDA PHARMACEUTICALS, INC., Nominal Defendant.	Civil Action No.:_____ **DEMAND FOR JURY TRIAL**

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Michael Bavaro ("Plaintiff"), by his undersigned attorneys, derivatively and on behalf of Nominal Defendant Vanda Pharmaceuticals, Inc. ("Vanda" or the "Company"), files this Verified Shareholder Derivative Complaint against the Defendants (as defined herein) for breaches of their fiduciary duties as members of the Board of Directors (the "Board") or officers of Vanda. Plaintiff alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which included, review and analysis of the following: Vanda's public documents and announcements; the Company's conference calls and press releases; U.S. Securities and Exchange Commission ("SEC") filings; press releases and news reports published regarding Vanda; corporate governance and other documents available on the Company's website; allegations made in pleadings filed in a lawsuit alleging federal securities violations against Vanda and defendants Mihael H. Polymeropoulos ("Polymeropoulos"), James P. Kelly ("Kelly"), Gian Piero Reverberi ("Reverberi"), and non-defendant Thomas E. Gibbs ("Gibbs") captioned, *Gordon v. Vanda Pharmaceuticals, Inc.*, Civil Action No. 1:19-cv-01108-FB-LB (E.D.N.Y.) (the "Securities Class Action"); allegations contained in pleadings filed in *U.S. ex rel. Gardner v. Vanda Pharmaceuticals*, No. 1:17-cv-00464 (APM) (D.D.C.) (the "Qui Tam Litigation"); the allegations contained in pleadings filed in *Vanda Pharmaceuticals, Inc. v. Food and Drug Administration,*, No. 19-cv-301 (JDB) (D.D.C.) (the "FDA Litigation"); drug labels, approval information, and other materials made publicly available by the U.S. Food and Drug Administration ("FDA"); and other publicly-available information about the Company.

NATURE OF THE ACTION

1. This is a shareholder derivative action brought on behalf of Nominal Defendant Vanda against the Individual Defendants seeking to remedy their breaches of fiduciary duty,

corporate waste, unjust enrichment, and violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act").

2. Vanda is a biopharmaceutical company that focuses on the development and commercialization of therapies to address high unmet medical needs and improve the lives of patients. The Company's marketed products include Hetlioz (tasimelteon), a product for the treatment of non-24-hour sleep-wake disorders ("Non-24"); and Fanapt (iloperidone), a product for the treatment of schizophrenia. From November 4, 2015 through February 11, 2019 (the "Relevant Period"), Vanda derived all of its revenue from sales of Fanapt and Hetlioz. In connection therewith, the Individual Defendants made materially false and misleading statements and omissions concerning a long-running, wide-spread, and systemic off-label marketing scheme and other prohibited marketing strategies that the Individual Defendants caused the Company to undertake to sell Fanapt and Hetlioz.

3. For Fanapt, Vanda trained its sales representatives to promote the drug off-label in a variety of ways, including: (i) marketing Fanapt to treat mental disorders other than schizophrenia; (ii) focusing on akathisia, a side effect of antipsychotics, in an effort to obtain sales to non-schizophrenia patients; (iii) providing unrealistic sales targets that required off-label promotion in order to be met; (iv) compensating sales representatives for off-label sales; (v) targeting pediatric patients as part of the marketing efforts for Fanapt even though the drug is only FDA-approved for use by adults; (vi) presenting Fanapt as a first line treatment even though it is only FDA-approved as a second line treatment, meaning it should not be used unless a patient has tried another antipsychotic first; (vii) downplaying the extent and severity of QT prolongation, a serious and sometimes fatal side effect of Fanapt; and (viii) promoting that Fanapt can be administered once-daily even though it is only FDA-approved to be taken twice-daily.

4. With regard to Hetlioz, although Vanda repeatedly acknowledged that the Non-24 drug was intended for use in only blind individuals, the Individual Defendants realized that the patient population of blind patients with Non-24 was very small, and therefore caused the Company to start targeting psychiatrists treating sighted patients for Hetlioz by at least November 2015. Indeed, the Individual Defendants focused their sales efforts for Hetlioz on sighted individuals who were having trouble sleeping – not those who received a doctor's diagnosis for Non-24, which can be tested for, but is exceedingly rare in sighted individuals. These efforts caused Hetlioz, which comes with a $180,000 price tag for an annual supply during the Relevant Period, to be marketed off-label during the Relevant Period.

5. In addition to Fanapt and Hetlioz, the Individual Defendants also made materially false and misleading statements and omissions concerning tradipitant, which was Vanda's most important drug in the clinical trial stage during the Relevant Period. Tradipitant is a small molecule neurokinin-1 receptor antagonist under clinical development for the treatment of chronic pruritus in atopic dermatitis and gastroparesis. Unbeknownst to the investing public, the FDA informed Vanda in May 2018 that if the Company wanted to do a study of tradipitant in humans for longer than three months, which was required for the drug to receive FDA approval, Vanda would need to conduct a nine-month non-rodent study for the purpose of ensuring that tradipitant is safe for humans.

6. The FDA told the Individual Defendants that if Vanda failed to do the required safety study, the FDA would enforce a clinical trial hold on tradipitant. A clinical trial hold is an order rarely issued by the FDA to delay or suspend a drug trial. Such an order would have been catastrophic for the Company. However, despite being fully aware of the FDA's position by May 2018, the Individual Defendants continued to conduct tradipitant studies lasting longer than three

months. Accordingly, in December 2018 the FDA ordered clinical trial holds for tradipitant, placing the commercial future of tradipitant in peril.

7. Thus, at all relevant times from May 2018 until the end of the Relevant Period, the Individual Defendants knew, or recklessly disregarded, that Vanda would not conduct the safety test for tradipitant as required by the FDA. Despite this, the Individual Defendants made, and caused Vanda to make, numerous statements to investors regarding the progress of clinical trials for tradipitant, omitting this critical information.

8. On February 5, 2019, the truth regarding tradipitant emerged when the Company commenced the FDA Litigation. The Individual Defendants' off-label promotion scheme for Fanapt and Hetlioz was further revealed in a short seller report by Aurelius Value, issued on February 11, 2019 (the "Aurelius Report").

9. The Company has been substantially damaged as a result of the Individual Defendants' knowing breaches of fiduciary duty and other violations of law. Therefore, Plaintiff brings this action against the Individual Defendants to remedy their misconduct.

JURISDICTION AND VENUE

10. Pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act, this Court has jurisdiction over the claims asserted herein for violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder. This Court has supplemental jurisdiction over the remaining claims under 28 U.S.C. §1367.

11. This court has jurisdiction over each defendant named herein because each defendant conducts business in this District or is an individual with sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

12. Venue is proper in this Court in accordance with 28 U.S.C. §1391 because: (i) one or more of the defendants either resides in or maintains executive offices in this District; (ii) a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to Vanda, occurred in this District; and (iii) defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

13. Moreover, Vanda's Fourth Amended and Restated Bylaws as of December 17, 2015 requires "the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the Corporation . . . ."

PARTIES

14. Plaintiff is a stockholder of Vanda, has been continuously since 2014, and continues to be a Vanda shareholder.

15. Defendant Vanda is a Delaware corporation that maintains its headquarters in Washington, D.C. It is a biopharmaceutical company that licenses, clinically develops, markets, and sells pharmaceutical drugs principally in the United States, including in New York. Vanda's common stock is traded on the NASDAQ securities exchange under the symbol "VNDA."

16. Defendant Polymeropoulos co-founded Vanda in 2003 and has served as the Company's President, Chief Executive Officer ("CEO"), and a director on Vanda's board of directors since May 2003. Defendant Polymeropoulos is a psychiatrist who holds a degree in medicine from the University of Patras. Defendant Polymeropoulos is named as a defendant in the

Securities Class Action. According to the Form DEF14A filed by Vanda with the SEC on April 25, 2019 (the "2019 Proxy"), Defendant Polymeropoulos received at least the following compensation during the Relevant Period:

2018	$4,284,676
2017	$3,797,395
2016	$7,185,457
TOTAL	$15,267,528

17. Defendant Kelly has served as the Company's Executive Vice President, Chief Financial Officer ("CFO"), and Treasurer since December 2010. Defendant Kelly has worked in the biotechnology and pharmaceutical industry since 1991. Defendant Kelly is named as a defendant in the Securities Class Action. Defendant Kelly received at least the following compensation during the Relevant Period:

2018	$2,238,830
2017	$2,298,739
2016	$2,189,029
TOTAL	$6,726,598

18. Defendant Reverberi has served as the Company's Senior Vice President and Chief Commercial Officer ("CCO") since December 2015. Prior to this role, defendant Reverberi served as the Company's Senior Vice President and European General Manager from September 2015 to December 2015. Defendant Reverberi is named as a defendant in the Securities Class Action. Defendant Reverberi received the following compensation during the Relevant Period:

2018	$2,275,881
2017	$2,065,473
2016	$1,734,494
TOTAL	$6,075,848

19. Defendant H. Thomas Watkins ("Watkins") has served as Chairman of the Board since March 2014.

20. Defendant Michael F. Cola ("Cola") has served on the Board since 2012. Defendant Cola served as a member of the Audit Committee of the Board during the Relevant Period.

21. Defendant Richard W. Dugan ("Dugan") has served on the Board since 2005, before the Company's initial public offering. Defendant Dugan served as Chairman of the Audit Committee of the Board during the Relevant Period.

22. Defendant Vincent J. Milano ("Milano") served on the Board from 2010 until his resignation at the 2019 Shareholder Annual Meeting held on June 13, 2019. Defendant Dugan served as a member of the Audit Committee of the Board during the Relevant Period.

23. Defendant Kenneth M. Bate ("Bate") served as a director of the Company from December 2015 until his resignation at the 2018 Shareholder Annual Meeting held on June 2018.

24. Defendants Polymeropoulos, Kelly, Reverberi, Watkins, Cola, Dugan, Milano, and Bate are collectively referred to herein as the "Individual Defendants."

25. Non-Defendant Gibbs served as the Company's Senior Vice President and CCO from April 2015 until his departure in December 2015. Defendant Gibbs did not previously work at Vanda before April 2015. Gibbs, who is currently the CCO of Optinose, Inc., a pharmaceutical

company, has spent his career working in the biotechnology and pharmaceutical industry. On December 21, 2015, Vanda filed a Form 8-K announcing, among other things, that Gibbs had resigned from Vanda after only eight months as the Company's CCO (the "12/21/15 Form 8-K"). The 12/21/15 Form 8-K further stated, among other things, that because Gibbs resigned, "he is not entitled to any severance or other post-termination benefits."

DUTIES OF THE INDIVIDUAL DEFENDANTS

26. By reason of their positions as officers or directors of the Company and because of their ability to control the corporate affairs and business of the Company, the Individual Defendants owed the Company and its shareholders fiduciary obligations of loyalty and due care, and they were and are required to use their best efforts to control and manage the Company in a fair, just, honest, and equitable manner.

27. The Individual Defendants were and are required to act in furtherance of the best interests of the Company and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to the Company and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

28. The Individual Defendants, because of their positions of control and authority as directors or officers of the Company, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein.

29. In addition, as officers or directors of a publicly held company, the Individual Defendants have a duty to promptly disseminate accurate and truthful information with regard to

the Company's operations, performance, management, projections, and forecasts so that the market price of the Company's stock will be based on truthful and accurate information.

30. To discharge their duties, the officers and directors of Vanda were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Vanda were required to, among other things:

a. ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

b. conduct the affairs of the Company in a lawful, efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

c. properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's financial results and prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

d. remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and

e. ensure that the Company was operated in a diligent, honest and prudent manner in compliance with all applicable federal, state and local laws, rules and regulations.

31. Each Individual Defendant, as an executive officer or director, owed to the Company and to its shareholders the fiduciary duties of loyalty and due care in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the

absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

32. The Company also maintains a Code of Business Conduct and Ethics (the "Code" or "Code of Conduct"). The Code sets forth legal and ethical standards of conduct for directors, officers, employees, and consultants of Vanda.

33. The purpose of the Code:

> The Code seeks to deter wrongdoing and to promote:
>
> (a) Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
>
> (b) Full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the "SEC") and in other public communications made by the Company;
>
> (c) Compliance with applicable governmental laws, rules and regulations including, without limitation, the rules and regulations of the SEC, the federal Occupational Safety and Health Act, the U.S. Foreign Corrupt Practices Act (the "FCPA"), the Federal Food, Drug, and Cosmetic Act and the rules and regulations of the U.S. Food and Drug Administration (the "FDA"), the anti-kickback provisions of the federal Social Security Act and Department of Health and Human Services Office of the Inspector General regulations, the federal False Claims Act, and comparable state laws.

34. Pursuant to the Code:

> **COMPLIANCE WITH APPLICABLE LAWS, RULES AND REGULATIONS**
>
> Obeying the law, both in letter and spirit, is the foundation on which the Company's ethical standards are built. You must comply with all applicable laws, rules and regulations of the cities, states, provinces and countries in which we operate. Although you are not expected to know the details of these laws, it is important to know enough to determine when to seek advice from managers or other appropriate personnel. If a law conflicts with a policy in the Code, you

must comply with the law. If you have any questions about these conflicts, ask your manager or the Company's Compliance Officer how to handle the situation.

ETHICAL CONDUCT

Beyond compliance with laws, the Company requires that all its employees, officers, and directors act in a manner that meets the highest standards of ethical behavior. This includes the obligation to avoid any actual or apparent conflicts of interest in personal and professional relationships. The honesty and integrity of our business conduct must not be compromised. The Company will not condone ethical violations for the sake of personal gain, personal advantage,
expediency, or perceived business advantage.

* * *

PUBLIC DISCLOSURE OF INFORMATION

(a) The federal securities laws require the Company to disclose certain information in various reports that the Company must file with or submit to the SEC. In addition, from time to time, the Company makes other public communications, such as issuing press releases.

(b) The Company expects all directors, officers and employees who are involved in the preparation of SEC reports or other public documents to ensure that the information disclosed in those documents is full, fair, accurate, timely and understandable.

(c) To the extent that you reasonably believe that questionable accounting or auditing conduct or practices have occurred or are occurring, report those concerns to the Company's Chief Executive Officer, Chief Financial Officer or Compliance Officer or in accordance with the Company's Whistleblower policy.

* * *

RECORD-KEEPING

(a) The Company requires honest and accurate recording and reporting of information in order to make responsible business decisions and to comply with the law. For example, employees who must report their hours worked must only report the true and actual number of hours worked (whether for purposes of individual pay or for purposes of reporting such information to customers). The Company also requires each director and employee to disclose any transaction or arrangement among such individual or any family member or affiliated entity of such individual, on the one hand, and any other director, employee or any family member or affiliated entity of such other individual, on the other hand, that in any way relates to or arises out of such individual's professional relationship with the Company.

(b) Many employees regularly use business expense accounts, which must be documented and recorded accurately in accordance with the Company's policies. If you are not sure whether you may seek reimbursement for a certain expense, ask your manager or the Compliance Officer.

(c) All of the Company's books, records, accounts and financial statements must be maintained in reasonable detail, must appropriately reflect the Company's transactions and must conform both to applicable legal requirements and to the Company's system of internal controls. Unrecorded or "off the books" funds or assets should not be maintained unless permitted by applicable law or regulation.

(d) Business records and communications often become public, and you should avoid exaggeration, derogatory remarks, guesswork or inappropriate characterizations of people and companies that can be misunderstood. This policy applies equally to e-mail, internal memos and formal reports. Records should always be retained or destroyed according to the Company's record retention policies. In accordance with those policies, in the event of litigation or governmental investigation, please consult the Company's Compliance.

* * *

COMPETITION AND FAIR DEALING

The Company seeks to outperform its competition fairly and honestly. Using or disclosing, or encouraging others to use or disclose, other companies' proprietary, confidential or trade secret information, without the owner's prior consent, and any theft or misappropriation of such information is strictly prohibited. You should endeavor to respect the rights of and deal fairly with the Company' customers, suppliers, competitors and employees.

* * *

SPECIAL ETHICS OBLIGATIONS FOR EMPLOYEES WITH FINANCIAL REPORTING RESPONSIBILITIES

(a) As a public company, it is important that the Company's filings with the SEC be accurate and timely. Depending on your position within the Company, you may be called upon to provide information to assure that the Company's public reports are complete, fair and understandable. The Company expects you to take this responsibility seriously and to provide prompt and accurate answers to inquiries related to the Company's public disclosure requirements.

(b) The Finance department bears a special responsibility for promoting integrity throughout the organization, with responsibilities to stakeholders both inside and outside the Company. The Chief Executive Officer, Chief Financial Officer, Controller and other finance personnel each have a special role both to adhere to these principles themselves and also to ensure that a culture exists throughout the

Company as a whole that ensures that fair and timely reporting of financial results and conditions.

(c) Because of this special role, the Chief Executive Officer, Chief Financial Officer or Controller and all other and all members of the Company's finance department are bound by the following Financial Officer Code of Ethics. Each agrees that he or she will:

(i) Act with honesty and integrity;

(ii) Avoid actual or apparent conflicts of interest in professional and personal relationships;

(iii) Provide information that is accurate, complete, objective, relevant, timely and understandable to ensure full, fair, accurate timely and understandable disclosure in reports and documents that the Company files with, or submits to, government agencies and in other public communications;

(iv) Accept responsibility for the full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed by the Company with the SEC;

(v) Bring promptly to the attention of the Chief Executive Officers, Chief Financial Officer or Compliance Officer any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings;

(vi) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee of the Company any significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data;

(vii) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee of the Company any fraud that involves management or other employees who have a significant role in the Company's financial reporting, disclosures or internal controls;

(viii) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee any information concerning any violation of this Code, including any conflicts of interest involving any employees who have a significant role in the Company's financial reporting, disclosures or internal controls; and

(ix) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee any information concerning a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business.

HEALTHCARE COMPLIANCE MATTERS

The Company is subject to a number of federal and state healthcare laws that are intended to, among other things, protect the health and well-being of patients that may be candidates for the Company's products. To ensure compliance with these laws, the Company has developed a Corporate Compliance Program, which consists of a series of policies and procedures. You are required to review and comply with these policies and procedures as they relate to your responsibilities within the company and to report any behaviors that may indicate non-compliance with such laws and/or the Company's Corporate Compliance Program. Copies of all Company policies and procedures are available on the Company intranet website.

(a) Interactions with Health Care Professionals. The federal Anti-Kickback Statute prohibits the offering of anything of value that is intended to influence a person to recommend, prescribe or purchase a product (including prescription medication) that may be reimbursed by the government (e.g., Medicare or Medicaid). The Company is committed to complying with these laws. Certain interactions with health care professionals and programs offered by the Company, including but not limited to speaker programs, consulting arrangements, and support for scientific and educational activities, need to be reviewed to ensure compliance with these laws. The Company's Corporate Compliance Program is consistent with the Code on Interactions with Healthcare Professionals adopted by the Pharmaceutical Research Manufacturers of America (PhRMA Code) and the Office of Inspector General's Compliance Program for Pharmaceutical Manufacturers (OIG Guidelines). If you are involved in commercial activities on behalf of the Company, you must comply with all Company policies and procedures with respect to interactions with health care providers.

(b) Product Information and Marketing. The Company is committed to facilitating the safe, effective, and knowledgeable use of our products consistent with the approved prescribing information, and to providing truthful, non-misleading information to physicians and patients that is supported by scientific evidence. We are also committed to abiding by the laws and regulations that apply to advertising and promotion of our products, including rules of the FDA and other regulatory authorities. If you are engaged in sales and marketing activities, you must comply with all Company policies and procedures with respect to promotional activities.

(c) Product Complaints and Adverse Events. Any employee, officer or director that becomes aware of a product complaint or adverse reaction to a Company product is required to report the information immediately to the Company's Chief Medical Officer in accordance with Company policy.

> (d) Patient Privacy. All employees, officers and directors must respect the privacy of the patient and the patient's relationship with his or her health care provider at all times. During the course of your business activities you may come into contact with, or have access to, a person's medical records or other medical or personal information. You must guard the confidentiality of all medical and personal information that you have access to in accordance with Company policy.
>
> (e) The False Claims Act. In cases of reimbursement for pharmaceutical products under a federal health care program, such as Medicare and Medicaid, the federal government considers the promotion of an unapproved drug or an unapproved use of an approved drug to be a false claim against the government and unlawful. Similarly, the provision of a kickback in connection with the promotion of the product is a violation of the False Claims Act. If you are engaged in sales and marketing activities, you must comply with all Company policies and procedures with respect to promotional activities.
>
> (f) Government Price Reporting Laws. The Company is party to state and federal pricing agreements, and is subject to price reporting obligations under those agreements and under various governing laws. These reporting requirements impact the level of rebates we pay to government programs, such as rebates under the Medicaid Rebate Act, certain state pharmaceutical assistance programs, and the reimbursement paid by the Medicare program for certain drug products. Any price reporting errors or omissions could lead to significant financial penalties, and in some cases, criminal penalties. The Company has developed and implemented policies and procedures that are designed to ensure price reporting accuracy and compliance, and you must comply with these policies if your responsibilities relate to government pricing.

35. In addition, the Company's Audit Committee is specifically tasked with the Board's oversight responsibilities. The purpose of the Audit Committee is governed by the Audit Committee Charter ("Charter") which states:

> The primary purpose of the Committee is to oversee (1) the integrity of the Company's financial statements and other financial information provided by the Company to its stockholders, (2) the Company's retention of its independent accountants, including oversight of the terms of their engagement and their performance, qualifications and independence (3) the performance of the Company's internal controls and disclosure controls, and (4) the Company's compliance with its ethics policies and legal and regulatory requirements. The Committee shall prepare the report of the Committee included in the Company's annual proxy statement as required by the Securities and Exchange Commission (the "SEC"). In addition, the Committee provides an avenue for communication among the independent accountants, financial management and the Board. The Committee's responsibility is one of oversight, recognizing that the

Company's management is responsible for preparing the Company's financial statements and that the independent accountants are responsible for auditing those financial statements. The independent accountants are ultimately accountable to the Committee and the Board for such accountants' audit of the financial statements of the Company.

36. The Charter states the responsibilities of the Audit Committee members as follows:

Financial Statements, Controls and Reports

11. Review and approve, if applicable, a timely analysis from management relating to any significant proposed or contemplated changes to the Company's accounting principles, policies, estimates, internal controls, disclosure controls, procedures, practices and internal auditing plans (including those policies for which management is required to exercise discretion or judgments regarding the implementation thereof).

12. Review disclosures made to the Committee by the Company's Chief Executive Officer and Chief Financial Officer during the certification process for the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q about any significant deficiencies or material weaknesses in the design or operation of internal controls or material weaknesses therein and any fraud involving management or other employees who have a significant role in the Company's internal controls, as contemplated by the Company's disclosure policies in effect from time to time.

13. Discuss with the Company's independent accountants their annual audit plan, including the scope of audit activities and all critical accounting policies and practices to be used, and any other matters required to be discussed by Statement on Auditing Standards No. 61, Communications with Audit Committees, as amended by Statement of Auditing Standards No. 90 and as it may be further modified or supplemented.

14. Periodically discuss with the Company's independent accountants, without management being present, (a) their judgments about the quality, appropriateness and acceptability of the Company's accounting principles and financial disclosure practices, as applied in its financial reporting, (b) the completeness and accuracy of the Company's financial statements, and (c) such matters as are required to be discussed with the Committee under generally accepted auditing standards.

15. Review the Company's annual and quarterly consolidated financial statements with management and the independent accountants prior to the first public release of the Company's financial results for such year or quarter and review any "pro forma" or "adjusted" non-GAAP information

included in such release. With the consent of the Committee, the Chair of the Committee may represent and act on behalf of the entire Committee for purposes of the review of any quarterly consolidated financial statements.

16. Review the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q in advance of such filings. With the consent of the Committee, the Chair of the Committee may represent and act on behalf of the entire Committee for purposes of the review of any Quarterly Reports on Form 10-Q.

17. Review the Company's accounting treatment of tax related matters, the presentation of tax matters in the footnotes of the financial statement, its compliance with applicable tax laws and regulations and any decisions by management regarding tax planning.

18. Meet periodically with management and/or the independent accountants to:

- review the annual audit plans of the independent accountants;
- discuss any significant matters arising from any audit or report or communication relating to the consolidated financial statements, including any material audit problems, disagreements or difficulties and responses by management;
- understand the significant judgments made and alternatives considered in the Company's financial reporting, including the appropriateness of the alternatives ultimately chosen; and
- discuss policies with respect to significant financial risks and exposures, if any, and the steps taken to assess, monitor and manage such risks.

21. Review with management, the Company's independent accountants and, to the extent applicable, the internal auditors (or other persons responsible for the Company's internal audit function): (a) the results of the annual audit of the Company and the independent accountants' procedures with respect to interim periods, including any significant findings, comments or recommendations of the independent auditors and, to the extent applicable, internal auditors (or other persons responsible for evaluating the Company's compliance with internal controls) together with management's responses thereto; and (b) any significant changes in the Company's accounting principles or the methods of applying the Company's accounting principles.

22. Review with the Company's external counsel any legal matters that could have a significant impact on the Company's financial statements, the Company's

compliance with applicable laws and regulations and inquiries received from regulators or governmental agencies.

23. Review the reports prepared by management, and attested to by the Company's independent accountants, assessing the adequacy and effectiveness of the Company's internal controls and procedures, prior to the inclusion of such reports in the Company's periodic filings as required under the rules of the SEC; the Committee will also meet separately with the independent accountants, with and without management present, to discuss the results of their examination.

Reporting and Recommendations

24. Direct the Company's independent accountants to review, before filing with the SEC, the Company's interim financial statements included in quarterly reports on Form 10-Q, using professional standards and procedures for conducting such reviews.

25. Determine, based on the reviews and discussions noted above, whether to recommend to the Board that the audited financial statements be included in the Company's Annual Report to Stockholders and on Form 10-K for filing with the SEC.

26. Prepare any report, including any recommendation of the Committee, required by the rules of the SEC to be included in the Company's annual proxy statement.

27. Maintain minutes or other records of meetings and activities of the Committee.

28. Report the Committee's activities to the Company's CEO and the Board on a regular basis, including with respect to any issues that arise regarding the quality or integrity of the Company's financial statements, the effectiveness of the Company's internal controls or disclosure controls, the performance and independence of the Company's independent accountants and any other issue that the Committee believes should be brought to the attention of the Board. Such reports may be made orally or in writing.

Other Responsibilities

29. Overseeing compliance with the disclosure requirements of the SEC, including disclosure of information regarding auditors' services, audit committee members, member qualifications and services.

30. Establish and maintain procedures for (a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls and auditing matters and business conduct or ethics violations and (b) the confidential, anonymous submission by employees of the Company of concerns

> regarding questionable accounting or auditing matters or business conduct or ethics violations.

37. In violation of the Charter, and their general duties as members of the Audit Committee, defendants Dugan, Cola, and Milano, who were members of the Audit Committee during the Relevant Period conducted little, if any, oversight of the Company's internal controls over public disclosures resulting in materially false and misleading statements regarding the Company's business, operational and compliance policies, and consciously disregarded their duties to monitor such controls over reporting. The Audit Committee members' complete failure to perform their duties in good faith resulted in misrepresentations to the SEC, the investing public, and the Company's shareholders.

38. In addition, as executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on NASDAQ, the Individual Defendants had a duty not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, so that the market price of the Company's common stock would be based upon truthful and accurate information. Accordingly, the Individual Defendants breached their fiduciary duties by knowingly or recklessly causing Vanda to make false and misleading statements of material fact about the Company's financials and about Vanda's maintaining adequate internal controls and compliance with applicable rules and regulations.

39. Each of the Individual Defendants further owed to Vanda and its shareholders the duty of loyalty requiring that each favor Vanda's interest and that of its shareholders over their

own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

SUBSTANTIVE ALLEGATIONS

COMPANY BACKGROUND

40. In early 2003, Vanda was co-founded by defendant Polymeropoulos after he left Novartis AG ("Novartis"). The Company purportedly focuses on developing and commercializing novel therapies to address unmet medical conditions.

41. Vanda became a publicly-traded company on April 18, 2006. At this time, the Company had no FDA-approved drugs and only three products in the clinical trial stage. The first drug, iloperidone, obtained FDA approval before the Relevant Period and became known as Fanapt. According to its FDA label, Fanapt is approved to be sold to treat "adults with schizophrenia."

42. The second drug, VEC-162, or tasimelteon, also obtained FDA approval before the Relevant Period and became known as Hetlioz. According to its FDA label, Hetlioz is approved to treat "Non-24-Hour Sleep-Wake Disorder." Non-24 is a rare circadian rhythm disorder that occurs mostly, if not fully, in blind individuals due to their internal clocks not being synched with the light and dark cycles of the day because they cannot perceive light.

43. The third drug, VSF-173, failed to reach certain milestones under Vanda's license agreement with Novartis. As a result, the Company lost its license for VSF-173 on November 3, 2008.

44. On April 12, 2012, Vanda entered into a license agreement with Eli Lilly and Company, which granted Vanda an exclusive worldwide license to develop and commercialize VLY-686, or tradipitant. During the Relevant Period, tradipitant was undergoing clinical trial testing for the purpose of obtaining FDA approval, but is not currently FDA-approved.

45. By November 2015, the beginning of the Relevant Period, Vanda's portfolio of FDA-approved products consisted only of Fanapt and Hetlioz. Vanda did not receive FDA approval to sell any drugs other than Fanapt or Hetlioz during the Relevant Period.

VANDA DERIVES ITS REVENUES SOLELY FROM SALES OF FANAPT AND HETLIOZ

46. According to the 2015 Form 10-K (defined below), Vanda's "net product sales consist of sales of HETLIOZ® and sales of Fanapt®." During the Relevant Period, there was no other contributors to Vanda's revenue other than the sales of Fanapt and Hetlioz.

47. During fiscal year 2015 ("FY15"), Vanda generated $109.925 million in revenue, of which sales of Fanapt consisted of $65.623 million in revenue and sales of Hetlioz consisted of $44.302 million in revenue.

48. During fiscal year 2016 ("FY16"), Vanda generated $146.017 million in revenue, of which sales of Fanapt consisted of $74.346 million in revenue and sales of Hetlioz consisted of $71.671 million in revenue.

49. During fiscal year 2017 ("FY17"), Vanda generated $165.083 million in revenue, of which sales of Fanapt consisted of $75.105 million in revenue and sales of Hetlioz consisted of $89.978 million in revenue.

50. During the fiscal year ended December 31, 2018 ("FY18"), Vanda generated $193.118 million in revenue, of which sales of Fanapt consisted of $77.283 million in revenue and sales of Hetlioz consisted of $115.835 million in revenue.

51. Accordingly, during the Relevant Period, marketing and selling Fanapt and Hetlioz represented the core of Vanda's operations and financial performance.

VANDA'S ILLEGAL OFF-LABEL PROMOTION SCHEMES FOR FANAPT AND HETLIOZ

52. The term "off-label marketing" or "off-label promotion" refers to marketing or promoting a drug for an indication *(e.g.,* a disease or symptom) that it has never received FDA approval to treat.

53. The FDA only approves drugs if they have been shown to be safe and effective for the specific indications that they are approved to treat.

54. The FDA does not regulate or control how FDA-approved drugs are prescribed by physicians once the drugs are marketed for sale by pharmaceutical companies. Thus, physicians are able, on their own volition, to prescribe drugs for off-label uses.

55. Nonetheless, it is illegal to actively market or promote drugs off-label. Indeed, at all relevant times Vanda was required to comply with the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), and related FDA regulations, which prohibit pharmaceutical companies from introducing drugs into interstate commerce for any intended use that the FDA has not determined to be safe and effective. *See* §§505(a), 515 (a), 501(f)(1), and 301(a) and (d), of the FD&C Act, and 21 U.S.C. §§355(a), 360e(a), 351(f)(1)) and 331(a) and (d). Thus, Vanda was legally prohibited from engaging in off-label marketing or promotion during the Relevant Period.

56. The FD&C Act and the FDA also prohibit pharmaceutical companies, like Vanda, from introducing misbranded drugs into interstate commerce. *See* §§502(o), 501(f)(1), 513(f)(1), 515, and 301(a) and (d) of the FD&C Act and 21 U.S.C. §§352(o), 351(f)(1), 360c(f)(1), 360e and 331(a) and (d)).

57. Further, FDA guidance requires that if a physician inquires with a pharmaceutical company sales representative about potential off-label uses for a drug, the sales representative "should refer such questions to a medical/scientific officer or department . . . and the officer or

department to which the referral is made should be separate from the sales and/or marketing department."

58. As explained herein, Vanda did not follow FDA guidance during the Relevant Period but rather Vanda trained its sales representatives to market and sell Fanapt and Hetlioz off-label.

59. Off-label drug promotion has, in recent years, become the focus of health care fraud enforcement efforts by federal and state authorities under the False Claims Act ("FCA") and related state statutes. In FCA cases, which often start as *qui tam* whistleblower complaints, off-label promotion for non-medically approved indications allows federal and state authorities to recover large monetary settlements (including treble damages) from drug companies for each instance of off-label promotion.

60. Accordingly, at all relevant times during the Relevant Period, any and all off-label promotion or marketing engaged in by Vanda violated the FD&C Act, the FCA, and FDA guidance and regulations.

VANDA OBTAINS ITS LICENSE TO MARKET AND SELL FANAPT SHORTLY BEFORE THE RELEVANT PERIOD

61. In June 2004, before Vanda went public, the Company entered into a sublicense agreement with Novartis to develop and commercialize Fanapt on behalf of Novartis.

62. When Vanda went public in April 2006, the Company explained to investors that Vanda believed that Fanapt would be effective in treating schizophrenia and bipolar disorder. Specifically, the Company stated in the Form 424B4 prospectus provided to investors, in pertinent part, that:

> *In addition to schizophrenia, we believe iloperidone may be effective in treating bipolar disorder. Most of the approved atypical antipsychotics have received*

> *approval for bipolar disorder subsequent to commercialization for the treatment of schizophrenia*. Iloperidone is ready for an initial Phase II trial in bipolar disorder.[1]

63. The reason why Vanda sought to receive FDA approval for Fanapt to treat both bipolar disorder and schizophrenia is because most antipsychotics – the drugs that Fanapt would directly compete with – are indicated for treating multiple related mental illnesses.

64. In addition, bipolar disorder is more than twice as prevalent in the United States as schizophrenia, which means that getting approval for bipolar disorder would vastly expand the pool of potential patients who could use Fanapt on-label. If Fanapt could only obtain approval for treating schizophrenia, it would be at a significant competitive disadvantage.

65. However, despite the importance of getting FDA approval to treat bipolar disorder, Vanda only submitted a new drug application ("NDA") for Fanapt to treat only schizophrenia, and ***not*** bipolar disorder or any other mental disorder. According to Vanda's Form 10-Q dated May 11, 2009, Vanda submitted the NDA for Fanapt on September 27, 2007.

66. In May 2009, the FDA approved Fanapt to treat only schizophrenia in adults, not to treat bipolar disorder, or any other mental illness, or even schizophrenia in adolescents or children. For this reason, Fanapt's FDA label only states that it is approved to treat "adults with schizophrenia."

67. Fanapt's FDA label also explains that Fanapt was approved as a second line treatment, which defendant Polymeropoulos acknowledged during the Jefferies Healthcare Conference held on June 9, 2016 (the "6/9/16 Conference") and the Oppenheimer Healthcare Conference held on March 21, 2017 ("3/21/17 Conference"). This meant that Fanapt was only

[1] Unless stated otherwise, all emphasis is added.

supposed to be prescribed by a doctor if a different antipsychotic had already been used by a patient and was shown to be ineffective or poorly tolerated.

68. The reason the FDA approved Fanapt as a second line treatment was because Fanapt users have a serious risk of developing QT prolongation, which is a side effect that can cause torsade de pointes type arrhythmia, which can result in sudden death.

69. Accordingly, Fanapt's FDA label contains a black box warning and states that other antipsychotics should be tried first. A black box warning appears on FDA labels to alert patients and doctors about serious adverse effects, or life-threatening risks, for a particular drug. According to the FDA, a black box warning is the most serious drug warning that the FDA can impose on a drug. At all relevant times, Fanapt had a black box warning due to its risk of causing QT prolongation.

70. In addition, Fanapt was approved by the FDA for a "recommended target dosage" of "12 to 24 mg/day administered twice daily." Fanapt's requirement to be taken twice-daily made it unlike most other antipsychotics, which are indicated by the FDA for once-daily treatment. The reason why most antipsychotics have a once-daily formulation is because patients with mental disorders have difficulties taking their medicine on a routine schedule. Prescribing mentally ill patients medicine that only requires being taken once a day increases the chances that the patient will stick with treatment.

71. After Fanapt received FDA approval, Vanda and Novartis entered into an amended sublicense agreement in October 2009 that gave Novartis exclusive commercialization rights to Fanapt. Thus, as of October 2009, Novartis was responsible for selling and marketing Fanapt in the United States. In return, Vanda received royalty payments from Novartis on sales of Fanapt.

72. In May 2014, Vanda commenced arbitration against Novartis related to the licensing of Fanapt. In December 2014, Vanda entered into a settlement agreement with Novartis and dismissed the arbitration proceeding.

73. Under the terms of the settlement agreement, Vanda obtained the rights to market and sell Fanapt in the United States. Accordingly, while Vanda began marketing and selling Fanapt in the United States for the first time in early 2015, Fanapt had been an FDA approved drug and was sold by Novartis since May 2009. Assuredly, this loss of the right to sell and market Fanapt did not phase Novartis given that after a strong start in January 2010, garnering $21 million in revenue, Fanapt's sales fell off a cliff. Its second quarter sales were a meager $0.7 million.[2]

THE INDIVIDUAL DEFENDANTS KNEW ABOUT, OR RECKLESSLY DISREGARDED, THE OFF-LABEL PROMOTION SCHEME FOR FANAPT

74. At all relevant times after Vanda obtained the rights to sell Fanapt in early 2015, the Individual Defendants engaged in an off-label promotion scheme to market and sell Fanapt. The Individual Defendants conducted this scheme because Fanapt was a difficult antipsychotic to sell on-label due to its limited indication (adults with schizophrenia), its status as a second line treatment, its risk of developing a serious side effect called QT prolongation, and its requirement to be administered twice-daily, as opposed to once-a-day, as described above.

75. Richard Gardner ("Gardner") is the relator in the Qui Tam Litigation and worked at Vanda as a Regional Business Leader ("RBL") for the mid-west region from November 16, 2015 until August 5, 2016. Gardner's territory included Illinois, Wisconsin, Michigan, Ohio, Western Pennsylvania, West Virginia, and Indiana. Prior to joining Vanda, Gardner worked in the pharmaceutical industry for over 23 years, including ten years at Pfizer / Pharmacia where he

[2] *Fanapt - Pharma's Biggest Flops*, FIERCEPHARMA, https://www.fiercepharma.com/special-report/fanapt-pharma-s-biggest-flops.

served as Regional Sales Trainer, Corporate Sales Trainer, and District Manager. Gardner believes that his departure from Vanda was due to his reluctance to comply with Vanda's off-label marketing promotion for Fanapt and Hetlioz.

76. Gardner filed the Qui Tam Litigation on March 10, 2017, in the United States Court for the District of Columbia, pursuant to the federal False Claims Act, 31 U.S.C. §3729, and analogous statutes of twenty-five States. Gardner's Qui Tam Litigation is currently pending against Vanda.

77. According to Gardner, RBLs were in charge of overseeing Vanda's 50 sales representatives for Fanapt, who were independent contractors hired through Publicis Touchpoint Solutions. Gardner states there were six RBLs during the Relevant Period, including himself and Jeff Bourgeois ("Bourgeois"). Bourgeois was an RBL at Vanda from November 2015 until June 2018, where he managed the Vanda sales representatives in his territory promoting Fanapt and Hetlioz. When Bourgeois was hired, his territory consisted of Louisiana, Arkansas, and Texas. However, in early 2017, Bourgeois' territory was changed to Texas and Oklahoma.

78. According to Gardner, RBLs reported directly to Vanda's National Sales Director. Vanda's National Sales Director, who was David James ("James") from January 2014 until July 2016, reported directly to Vanda's CCO, meaning initially non-defendant Gibbs and then subsequently defendant Reverberi. Vanda's CCO reported directly to Vanda's CEO, defendant Polymeropoulos. According to Gardner, the RBLs participated in weekly conference calls with James and Paul Ramirez ("Ramirez"), Head of Sales, to discuss the marketing and promotion of Fanapt and Hetlioz, which defendant Polymeropoulos would periodically join. According to Gardner, several times per year the RBLs would also attend in-person meetings with defendant Polymeropoulos and other Vanda senior executives in Washington, D.C.

79. When Vanda began marketing and selling Fanapt in early 2015, it only had 12 sales representatives covering the drug. These 12 sales representatives were termed the "Fanapt 12" by defendant Polymeropoulos.

80. The Fanapt 12 were focused on selling Fanapt to psychiatrists in New York City and St. Louis and were overseen by one RBL.

81. The Individual Defendants decided to expand the sales force for Fanapt in November 2015 to increase the Company's footprint throughout the United States. To that end, Vanda hired: Gardner; Bourgeois; two other RBLs; promoted one of the Fanapt 12 to RBL; and 39 new sales representatives in November 2015. This brought the sales team for Fanapt to 50 sales representatives and six RBLs as of November 2015. These 50 sales representatives were termed the "Fanapt 50" by defendant Polymeropoulos.

82. The six RBLs reported directly to James. According to Gardner and Bourgeois, James reported directly to the CCO (non-defendant Gibbs and then defendant Reverberi).

83. In addition, according to Gardner and Bourgeois, before the Relevant Period Vanda hired a consultant, Ramirez, an attorney, to assist James with promoting and selling Fanapt. According to Gardner and Bourgeois, Ramirez served as a consultant to Vanda at least until Bourgeois left Vanda in June 2018.

84. According to Gardner and Bourgeois, Ramirez was hired directly by defendant Polymeropoulos to serve as his consultant. Gardner and Bourgeois understood that Vanda specifically structured Ramirez's role with the Company so as to not have a formal employment relationship. Nonetheless, according to Gardner and Bourgeois, Ramirez reported directly to defendant Polymeropoulos and maintained an office in the Company's Washington, D.C. headquarters.

85. The Fanapt 50, the RBLs, and Vanda senior management, including defendant Polymeropoulos, attended a five-day national Fanapt launch meeting from November 30, 2015 to December 4, 2015, at the Fairmount Hotel in Washington, D.C. (the "November 2015 Meeting").

86. According to Gardner, the following members of Vanda's senior management were in attendance at the November 2015 Meeting: defendant Polymeropoulos, defendant Kelly, non-defendant Gibbs, defendant Reverberi, James, and Ramirez.

87. According to Gardner, Vanda's senior management conducted Fanapt sales training at the November 2015 Meeting.

88. Fanapt was a difficult drug for the Fanapt 50 to market and sell on-label. One of the main reasons is because Fanapt's competitor drugs were indicated to treat not only schizophrenia, but also other related mental illnesses such as bipolar disorder. Fanapt, however, was only approved to treat schizophrenia.

89. Nonetheless, at the November 2015 Meeting, Vanda's senior management trained its Fanapt sales force to market and sell Fanapt off-label for mental illnesses related to schizophrenia, especially bipolar disorder. According to Gardner and Bourgeois, the Fanapt 50 were trained at the November 2015 Meeting to promote and sell Fanapt regardless of the underlying condition it was being prescribed to treat.

90. According to Gardner, during the November 2015 Meeting, defendant Polymeropoulos told the Fanapt 50 and the RBLs that, because it was very difficult to get schizophrenia drugs approved by the FDA, doctors would understand that if Fanapt was approved to treat schizophrenia this meant Fanapt would also be effective in treating other mental health disorders, including bipolar disorder and depression.

91. According to Bourgeois, Vanda's sales force for Fanapt was trained to convince doctors that Fanapt was just as effective as other antipsychotics that treat both schizophrenia and bipolar disorder, without regard to whether Fanapt was being prescribed to treat schizophrenia, meaning on-label, or to treat bipolar disorder or another mental illness, meanings off-label.

92. According to Gardner, the Fanapt sales representatives were trained to avoid the subject of Fanapt being indicated only for schizophrenia. Gardner recounts that the sales aide for Fanapt distributed by Vanda to its sales representatives (the "Fanapt Sales Aide") specifically directed the sales representatives to push Fanapt even if a doctor stated he or she does not have schizophrenia patients.

93. According to Gardner, who retained a copy of the Fanapt Sales Aide that is referenced in the complaints in the Qui Tam Litigation, the Fanapt Sales Aide provided the following question and answer scenario, which was the very first such example given in the "overcoming objections" section: the doctor objection is "I don't see any/a lot of patients with schizophrenia" and Vanda's preferred response is "You don't see a lot of schizophrenia but you do use atypical antipsychotics, correct?" Gardner recounts that the sales training for the Fanapt sales representatives primarily focused on this portion of the Fanapt Sales Aide.

94. According to Gardner and Bourgeois, during the November 2015 Meeting, the Fanapt sales representatives role-played mock sales calls for Vanda's senior management. On the occasions where the sales representative would fail to mention schizophrenia, Vanda's senior management would not correct the sales representative or instruct him or her to mention the need to discuss schizophrenia. In fact, according to Gardner and Bourgeois, they felt that avoiding the word schizophrenia was viewed as a positive by Vanda's senior management.

95. According to Gardner, the Fanapt 12 also participated in the November 2015 Meeting. Gardner recounts that the Fanapt 12 described marketing and promoting Fanapt off-label in a manner similar to the training at the November 2015 Meeting for the Fanapt 50.

96. Further, part of Gardner's job at the November 2015 Meeting was to certify that sales representatives were properly trained to sell and promote Fanapt. To that end, Gardner was responsible for meeting with and grading a Fanapt 12 sales representative from New York. During the meeting, Gardner determined that the New York sales representative was engaging in off-label promotion and Gardner refused to certify the sales representative.

97. Thereafter, Gardner recounts that James and Ramirez expressed annoyance at Gardner's decision to not certify the New York sales representative, even after Gardner explained his reasoning. According to Gardner, the New York sales representative went in for testing again at the November 2015 Meeting before James, without Gardner, and the New York sales representative was certified.

98. According to Gardner and Bourgeois, Vanda encouraged its sales representatives to market Fanapt by promoting its propensity for not causing akathisia, which is a movement disorder characterized by a feeling of inner restlessness that is a common side effect of antipsychotics. Fanapt has a relatively low incidence of akathisia compared to other antipsychotics.

99. According to Gardner and Bourgeois, Vanda improperly used Fanapt's low incidences of akathisia to promote Fanapt off-label for the treatment of non-schizophrenia mental disorders. For example, the Fanapt Sales Aide provided Vanda's preferred response to the doctor objection that "Fanapt has only one indication," as follows:

> I understand that other antipsychotics have more than one indication. Can you think of any of your adult schizophrenia patients who are experiencing inner restlessness,

> agitation or other treatment-induced movement disorders on their current medication?
>
> *The Fanapt efficacy and tolerability profile, including its placebo-like rate of akathisia make it an option for patients who need to switch from one antipsychotic to another*.

100. According to Gardner and Bourgeois, the point that Vanda sought to impart on its Fanapt sales representatives was that Fanapt should be promoted as an alternative to all antipsychotics, regardless of whether the patient has schizophrenia, because Fanapt reduces the effects of akathisia.

101. To that end, according to Gardner, the Fanapt Sales Aide included the following additional preferred Vanda responses to the doctor objection that: "I don't see any/a lot of patients with schizophrenia," as follows: "Akathisia is a drug-induced side effect that can necessitate a treatment switch" and "Fanapt offers atypical antipsychotic efficacy with placebo-like rates of Akathisia."

102. According to Gardner and Bourgeois, by shifting the focus to akathisia and away from the doctor's stated concern that Fanapt would not be appropriate for his or her patients because they do not have schizophrenia, Vanda was promoting and marketing Fanapt off-label.

103. According to Bourgeois, defendant Polymeropoulos informed him during the November 2015 Meeting that every patient with akathisia should be on Fanapt.

104. According to Gardner, Vanda's focus on akathisia at the expense of schizophrenia resulted in objections to Vanda's marketing strategy by Kate Holland ("Holland"), Vanda's Vice President of Sales and Marketing from May 2012 to January 2016.

105. According to Gardner, defendant Polymeropoulos asked Holland to alter the marketing strategy for Fanapt to make it more aggressive. According to Gardner, Holland resigned in January 2016 after refusing defendant Polymeropoulos's request.

106. Also departing Vanda around this time was non-defendant Gibbs, who only started working at Vanda in April 2015. According to the 12/21/15 Form 8-K, Gibbs resigned after only eight months and forfeited his right to any severance or other post-termination benefits typically afforded to departing corporate executives. According to the 12/21/15 Form 8-K, defendant Reverberi immediately replaced Gibbs as Vanda's CCO.

107. Vanda also ensured that Fanapt would be promoted off-label because it trained sales representatives to convince doctors to switch to Fanapt from Risperidone, Latuda and Saphris – competitor antipsychotics that are FDA-approved to treat both schizophrenia and bipolar disorder.

108. According to Gardner and Bourgeois, Vanda senior management set sales goals for the Fanapt 50 based on the total market for antipsychotics without accounting for the fact that competitor drugs treat more indications than schizophrenia. According to Gardner and Bourgeois, this resulted in the Fanapt 50 having to promote Fanapt off-label or they would be unable to meet their sales goals because Fanapt could only treat a small portion of the relevant antipsychotic market on-label.

109. According to Gardner and Bourgeois, the RBLs, defendant Reverberi, James, and Ramirez participated in a conference call in June 2016 where, among other things, defendant Reverberi confronted the RBLs for not growing the sales of Fanapt faster. Several RBLs expressed frustration at the fact that Fanapt is only approved for one indication, per FDA rules, thereby limiting the pool of potential sales, to which defendant Reverberi responded "doctors can use Fanapt anywhere they want." Defendant Reverberi warned the RBLs on the call that their failure to increase Fanapt sales would jeopardize their jobs. After the conference call, Gardner and Bourgeois discussed whether defendant Reverberi had threatened them.

110. According to Bourgeois, he participated in a call with defendant Reverberi in June 2018 to discuss the Fanapt 50's inability to grow Fanapt prescriptions at the rate desired by Vanda's senior management. During this meeting, Bourgeois explained to defendant Reverberi that doctors were reporting that they were having extreme difficulties getting Fanapt approved by insurers because it was being prescribed off-label. In response, defendant Reverberi told Bourgeois that he did not believe Bourgeois, and asked Bourgeois what his plan was to turn around Fanapt sales.

111. According to Bourgeois, on one occasion in early 2018, Kate Arnold ("Arnold"), Vanda's Head of Compliance from February 2017 to the present, contacted Bourgeois after reviewing his sales representative reports because Bourgeois had written that sales representatives need to "push" doctors to prescribe Fanapt. Bourgeois included this language in his sales representative reports because that is what he was instructed to do by Tom Griffin ("Griffin"), Vanda's Vice President of Sales from 2017 to the present.

112. According to Bourgeois, Griffin was the permanent replacement for James, who departed from Vanda in July 2016. Bourgeois recounts that, like James, Griffin reported directly to defendant Reverberi during the Relevant Period.

113. According to Bourgeois, Arnold asked him to change this language because defendant Polymeropoulos was concerned about being sued by the government. Arnold further stated that Bourgeois was not the only RBL with this issue, and that she had spoken to other RBLs about changing similar language regarding pushing doctors to prescribe Fanapt.

114. According to Bourgeois, during early 2018, defendant Reverberi would inquire about how Bourgeois could get more Fanapt prescriptions from Dr. Boris Rubashkin ("Rubashkin"), a psychiatrist in Houston, Texas. Rubashkin was a large prescriber of Fanapt.

Brandy Barrington ("Barrington"), who was employed at Vanda from January 2016 to September 2018, was the Vanda sales representative responsible for interacting with Rubashkin. Bourgeois informed defendant Reverberi that Rubashkin had informed Barrington that he was already using Fanapt in every schizophrenia patient he had in his practice. Nonetheless, defendant Reverberi pushed Bourgeois to find a way to increase Fanapt prescriptions from Rubashkin, even though Bourgeois made it clear that there were no additional schizophrenia patients to add from Rubashkin's practice.

115. Vanda's intent to promote Fanapt off-label is also illustrated by how it compensated the Fanapt 50, which was to pay them on, to use Vanda's terminology, "total dirt." This meant that Vanda paid its sales representatives for every Fanapt prescription written in their territory, regardless of the condition it was written to treat, meaning they were paid for both on-label and off-label sales.

116. On several occasions during his employment with Vanda, Gardner stated to Vanda senior management that incentive compensation should not be based on total dirt and, instead, should only be based on approved call targets only, meaning doctors treating adult schizophrenia patients.

117. Gardner made this recommendation because he was concerned that paying sales representatives on total dirt incentivized off-label promotion. In fact, Gardner stated to Ramirez on one occasion that "Vanda is paying for off-label promotion" and "the sales goals are based on illegitimately earned prescriptions." In response, Ramirez warned Gardner not to use the word "illegitimate" again and told Gardner not to bring up the off-label topic again and not to send Ramirez any emails about paying on total dirt.

118. According to Bourgeois, in a meeting with Griffin and the RBLs in April 2018, the RBLs expressed concern about paying Fanapt sales representatives on total dirt. During this discussion, Griffin stated that the decision to pay on total dirt was made by senior management, and it was not changing.

119. The Individual Defendants knew, or recklessly disregarded, that Fanapt was being promoted off-label because, according to Gardner and Bourgeois, Vanda's senior management had access to information apprising them of the precise volume and percentage of Fanapt sales that were made off-label. According to Gardner, early in his employment at Vanda he was informed by senior management that the Company received ICD-9 data for each prescription for Fanapt.[3] This ICD-9 data consisted of the indication each Fanapt prescription was written for (the ICD-9 diagnosis code) and the dosage amount (the NDC code). According to Bourgeois, Vanda's senior management would know exactly how many Fanapt prescriptions were being written off-label by viewing the ICD-9 data that the Company routinely received.

120. In addition, Vanda's senior management was informed by at least one Fanapt sales representative that Fanapt prescriptions were being written off-label during the Relevant Period. According to Gardner, in March 2016, Dallas Medenwald ("Medenwald"), a member of the Fanapt 50 who covered the state of Indiana, called Gardner because the Indiana Medicaid program was changing its coverage to no longer reimburse for off-label antipsychotics, resulting in a loss of 400 prescriptions per month in Indiana.

121. Vanda also engaged in off-label promotion of Fanapt during the Relevant Period by targeting children with schizophrenia, instead of the adults whom Fanapt was approved by the

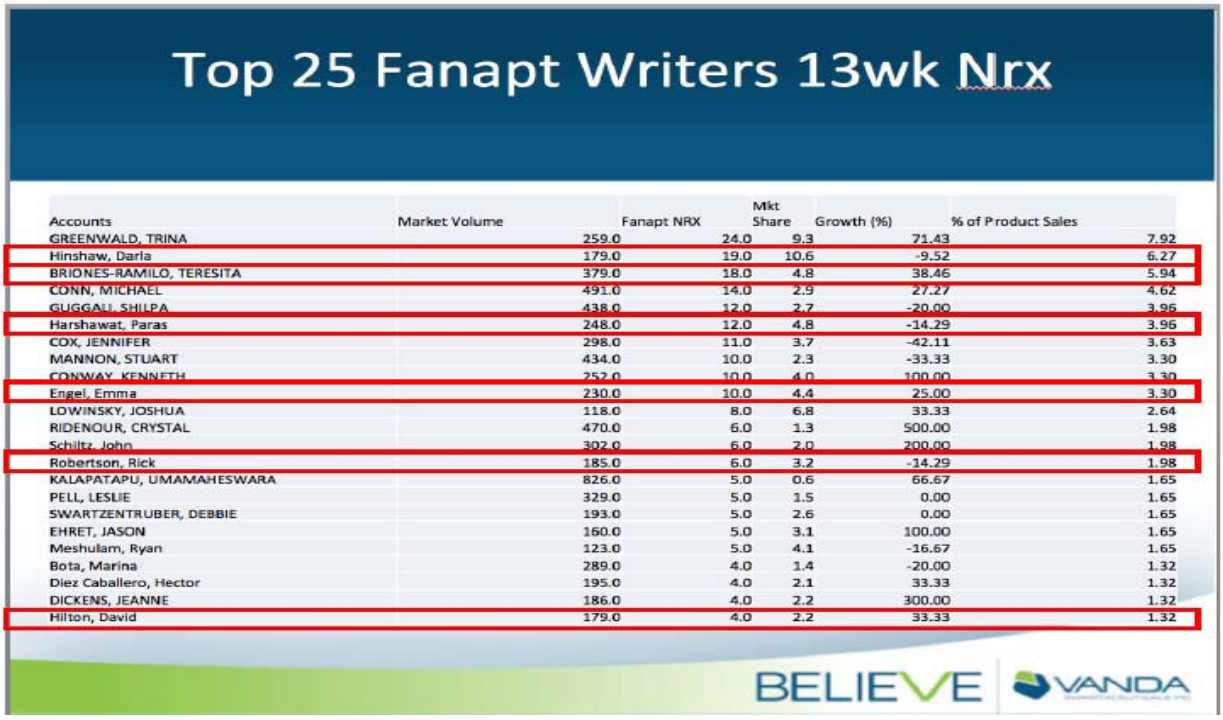
[3] ICD-9 is a list of codes corresponding to diagnoses and procedures that are entered into a patient's electronic health record and are used for diagnostic, billing, and reporting purposes.

FDA to treat. According to Gardner, the 400 prescriptions lost by Medenwald in Indiana all came from child psychiatrists who were prescribing Fanapt off-label to pediatric patients. Gardner confirmed that James and Ramirez were told that the reason why the 400 lost prescriptions in Indiana were off-label was because they were prescribed to pediatric patients.

122. According to Gardner and Bourgeois, Vanda senior management required each of the Fanapt 50 to target the top 25 prescribers of all antipsychotics in their territory, with the instruction to focus their sales efforts on convincing these doctors to prescribe Fanapt.

123. According to Gardner and Bourgeois, these top 25 prescribers were placed in charts by the Company and the charts often included child psychiatrists who, by definition, could not prescribe Fanapt on-label because they did not treat adults.

124. For example, in the complaints in the Qui Tam Litigation, Gardner provided the following top 25 chart for Vanda's Indiana territory, with the child psychiatrists highlighted:



Accounts	Market Volume	Fanapt NRX	Mkt Share	Growth (%)	% of Product Sales
GREENWALD, TRINA		259.0	24.0	9.3	71.43	7.92
Hinshaw, Darla		179.0	19.0	10.6	-9.52	6.27
BRIONES-RAMILO, TERESITA		379.0	18.0	4.8	38.46	5.94
CONN, MICHAEL		491.0	14.0	2.9	27.27	4.62
GUGGALI, SHILPA		438.0	12.0	2.7	-20.00	3.96
Harshawat, Paras		248.0	12.0	4.8	-14.29	3.96
COX, JENNIFER		298.0	11.0	3.7	-42.11	3.63
MANNON, STUART		434.0	10.0	2.3	-33.33	3.30
CONWAY, KENNETH		252.0	10.0	4.0	100.00	3.30
Engel, Emma		230.0	10.0	4.4	25.00	3.30
LOWINSKY, JOSHUA		118.0	8.0	6.8	33.33	2.64
RIDENOUR, CRYSTAL		470.0	6.0	1.3	500.00	1.98
Schiltz, John		302.0	6.0	2.0	200.00	1.98
Robertson, Rick		185.0	6.0	3.2	-14.29	1.98
KALAPATAPU, UMAMAHESWARA		826.0	5.0	0.6	66.67	1.65
PELL, LESLIE		329.0	5.0	1.5	0.00	1.65
SWARTZENTRUBER, DEBBIE		193.0	5.0	2.6	0.00	1.65
EHRET, JASON		160.0	5.0	3.1	100.00	1.65
Meshulam, Ryan		123.0	5.0	4.1	-16.67	1.65
Bota, Marina		289.0	4.0	1.4	-20.00	1.32
Diez Caballero, Hector		195.0	4.0	2.1	33.33	1.32
DICKENS, JEANNE		186.0	4.0	2.2	300.00	1.32
Hilton, David		179.0	4.0	2.2	33.33	1.32

125. In addition, Vanda had a competition for the Fanapt 50 called "10 to win," which paid an additional bonus every four to six weeks to the sales representative who had the most new prescription growth from a list of ten physicians in their territory chosen by the sales representatives. According to Gardner and Bourgeois, the "10 to win" lists contained child psychiatrists who, by definition, cannot prescribe Fanapt on-label because they do not treat adults.

126. For example, in the complaints in the Qui Tam Litigation, Gardner provided the following "10 to win" chart for Vanda's Indiana territory, with the child psychiatrists highlighted:

10 to Win (Current)

		Fanapt			
Actions Accounts	Market Volume	NRX	Mkt Share	Growth (%)	% of Product Sales
CONN, MICHAEL	495.0	16.0	3.23%	60.00%	19.75%
RIDENOUR, CRYSTAL	463.0	5.0	1.08%	150.00%	6.17%
MANNON, STUART	430.0	10.0	2.33%	0.00%	12.35%
SINGH, SURJIT	423.0	3.0	0.71%	100.00%	3.70%
KHAN, SYED	273.0	1.0	0.37%	-50.00%	1.23%
GREENWALD, TRINA	260.0	21.0	8.08%	40.00%	25.93%
CARTER, MICHELLE	255.0	3.0	1.18%	0.00%	3.70%
CONWAY, KENNETH	254.0	11.0	4.33%	100.00%	13.58%
Robertson, Rick	185.0	8.0	4.32%	33.33%	9.88%
REEF, MARK	184.0	3.0	1.63%	-40.00%	3.70%

BELIEVE VANDA

127. By allowing child psychiatrists to be included in the Company's target lists, Gardner and Bourgeois understood that the Individual Defendants intended for Vanda's sales representatives to promote Fanapt off-label.

128. According to Gardner, who retained copies of the top 25 and "10 to win" charts that are referenced in the complaints in the Qui Tam Litigation, these charts were available to everyone in Vanda's senior management and went right up to defendant Polymeropoulos.

129. It is reasonable to assume that if senior management knew of Fanapt being prescribed off-label, the members of the Board knew, and condoned, the scheme as well.

130. Another type of off-label promotion that Vanda engaged in for Fanapt during the Relevant Period involved promoting the drug as a first line treatment despite Fanapt only being approved by the FDA as a second line treatment.

131. According to Gardner and Bourgeois, during the November 2015 Meeting, defendant Polymeropoulos told the RBLs that if Fanapt were approved in November 2015 that it would be approved as a first line drug. For this reason, the Fanapt 50 received no training on ensuring that the patients being prescribed Fanapt had tried another antipsychotic first. In fact, according to Gardner, defendant Polymeropoulos stated at the November 2015 Meeting that most patients will have tried other drugs before being prescribed Fanapt, meaning sales representative did not need to inquire about it.

132. According to Bourgeois, the fact that Fanapt was a second line treatment was not included in any of the promotional materials provided to Fanapt's sales representatives.

133. Even worse, according to Bourgeois, during a 2017 conference call, Ramirez stated to Fanapt's sales representatives that Fanapt was a "first in class" drug. Bourgeois recounts being confused and concerned by this statement because Fanapt's FDA label clearly describes the drug as a second line treatment.

134. Notwithstanding the seriousness of QT prolongation as a side effect and Fanapt's black box warning, according to Gardner, the Fanapt Sales Aide instructed sales representatives to downplay this risk, stating, in pertinent part, as follows:

> *If Fanapt was approved today, it would not have received the QTc Interval Prolongation warning*. When the FDA approved Fanapt years ago, there was very little data about QTc Interval Prolongation so it was blown out of proportion. *Now, it is no longer a concern and if Fanapt were approved today it would not have the QTc Prolongation side effect warning*.

135. According to Gardner, at the November 2015 Meeting, sales representatives were trained by defendant Polymeropoulos to tell doctors that Latuda and Saphris do not have QT prolongation warnings because those drugs were approved years after Fanapt and the FDA no longer considers QT prolongation a serious issue.

136. Gardner's contemporaneous notes from a manager meeting he participated in while employed at Vanda confirm that Vanda was training its sales representatives to downplay, or even omit, the risk of developing QT prolongation posed by Fanapt. As stated in the complaints in the Qui Tam Litigation, these notes stated, in pertinent part, that:

> Any A-Typical launched post Latuda will no longer have QT Prolongation as part of the [package insert] as [the] *FDA realizes [QT Prolongation] is no long worth noting*. [The number of patients experiencing QT Prolongation] are too small to be an issue.

137. According to Bourgeois, Vanda did not address QT prolongation with Fanapt's sales representatives other than defendant Polymeropoulos mentioning at the November 2015 Meeting that it was no longer a relevant concern.

138. According to Gardner and Bourgeois, by not taking steps to properly train Fanapt's sales representatives on the risk of QT prolongation, and the related designation of Fanapt as a second line treatment, Vanda was promoting Fanapt off-label because sales representatives were promoting it as a first line treatment.

139. Vanda also engaged in off-label promotion of Fanapt during the Relevant Period by training its sales representatives to market Fanapt as being a once-daily drug, even though Fanapt's FDA label required Fanapt to be taken twice a day.

140. Fanapt's twice daily usage put it at a disadvantage compared to other antipsychotic medications, such as Risperidone and Latuda, which are once-daily formulations. According to Gardner, doctors prefer once-daily antipsychotics because patients with a mental illness are less likely to stay compliant with a medication schedule that requires multiple doses each day.

141. According to Gardner, during the November 2015 Meeting, defendant Polymeropoulos told the RBLs and the Fanapt 50 that Fanapt should have been approved for a once-

daily dosing and "many people have told me that I should go back to the FDA and request approval for QD [once a day] dosing for Fanapt because Fanapt's half-life of 23 1/2 hours is so long."

142. According to Gardner, based on this comment, Vanda's sales representatives were trained to promote Fanapt by stating that its 23 1/2 hour half-life meant that Fanapt could be prescribed once daily, despite the FDA label. In fact, during the November 2015 Meeting, Gardner recalled defendant Polymeropoulos stating that "[d]octors will ask you if Fanapt can be dosed once daily because of the long half-life and you know what the answer to that question is? It can be!"

143. According to Gardner, in the overcoming objections portion of the Fanapt Sales Aide, Vanda provided the following guidance if a doctor stated that Fanapt's "dosing is not practical for schizophrenia patients," as follows: "Fanapt half-life is 18-26 hours." According to Gardner, sales representative understood this to mean that Fanapt should be promoted as a once daily drug, notwithstanding Fanapt's FDA label.

144. Taken collectively, the above allegations demonstrate that the Individual Defendants knew, or recklessly disregarded, that Vanda engaged in a multifaceted off-label promotion scheme for Fanapt during the Relevant Period, including: (i) marketing Fanapt to treat mental disorders other than schizophrenia; (ii) focusing on akathisia to distract doctors from the underlying condition Fanapt was being used to treat; (iii) providing unrealistic sales targets that required off-label promotion in order to be met; (iv) compensating sales representatives for off-label sales; (v) targeting pediatric patients as part of the sales efforts for Fanapt; (vi) presenting Fanapt as a first line treatment; (vii) downplaying the extent and severity of QT prolongation; and (viii) promoting that Fanapt can be administered once-daily.

145. Moreover, Vanda's long-running off-label promotion scheme for Fanapt rendered false and misleading the repeated statements made by Defendants during the Relevant Period

regarding the Fanapt 50, how Fanapt was being promoted and sold, and other representations in Vanda's SEC filings regarding Fanapt's marketing. By repeatedly speaking about the topic of Vanda's marketing and promotional efforts for Fanapt, the Individual Defendants had a duty to speak fully and truthfully to the public and investors. Because the Individual Defendants failed to disclose the off-label promotion scheme for Fanapt, these statements omitted material information from Vanda's investors, thereby rendering statements made by the Individual Defendants during the Relevant Period materially false and misleading.

THE FDA APPROVES HETLIOZ SHORTLY BEFORE THE RELEVANT PERIOD

146. On May 31, 2013, Vanda submitted an NDA to the FDA "to support marketing of tasimelteon, a melatonin agonist, for the treatment of Non-24 hour sleep-wake disorder (Non-24) in totally blind patients."

147. According to the FDA's Summary Review of the Hetlioz NDA, Non-24 occurs principally, if not totally, in blind individuals. Specifically, the FDA's Summary Review states, in pertinent part, that:

> Non-24 hour sleep-wake disorder is characterized by a mismatch between the timing of the sleep-wake cycle and the 24-hour day because of a lack of environmental light input *in completely blind individuals*. As the individual "biological clock" runs longer than 24 hours in most people, the absence of light input creates a cyclical misalignment of sleep and wakefulness with the 24-hour day.

148. According to the National Sleep Foundation ("NSF"), which is a nonprofit foundation whose largest single source of funding is pharmaceutical companies, Non-24 requires a formal diagnosis by a doctor.

149. In particular, according to the NSF, "blood, saliva, or urine should be collected [by a doctor] over several weeks to look for circadian biochemical chemical rhythms that can determine for sure whether the clock is exhibiting a non-24-hour rhythm." This is because Non-24 "has been misdiagnosed for other sleep deprivation or non-related psychiatric disorders in the past." Thus,

according to the NSF, Non-24 should be tested for and observed by medical professionals before an individual is determined to have Non-24, as opposed to a different kind of sleep disorder. Non-24 rarely, if ever, occurs in sighted individuals.

150. Before the Relevant Period, the Individual Defendants repeatedly acknowledged that Non-24 rarely, if ever, occurs in sighted individuals. For example, in an investor presentation that Vanda filed on Form 8-K on March 9, 2010, the Company described Non-24 as a disorder that "*[o]ccurs almost entirely in subjects who are totally blind* and lack the light sensitivity necessary to reset the circadian clock."

151. In support of the NDA for Hetlioz, Vanda conducted two clinical trials involving Hetlioz. According to the FDA label for Hetlioz, both studies involved "totally blind patients with Non-24."

152. In a January 26, 2012, press release issued by Vanda, announcing initial trial results from one of the clinical trials referenced in the FDA label for Hetlioz, Vanda stated, in pertinent part, as follows:

> *Tasimelteon is a circadian regulator in development for the treatment of Non-24-Hour Disorder in totally blind individuals with no light perception.*
>
> * * *
>
> Circadian regulation is necessary for the treatment of Non-24-Hour Disorder and it is predictive of a beneficial effect on both nighttime sleep and daytime naps. While light resets the body clock in sighted individuals, keeping it synchronized with the 24-hour day, this effect is lost in totally blind individuals with no light perception.

153. On November 14, 2013, Vanda issued a press release, which was subsequently filed on Form 8-K on November 15, 2013 (the "11/15/13 Form 8-K"), announcing that the FDA had voted to recommend the approval of Hetlioz "for the treatment of Non-24-Hour Disorder (Non-24) in the *totally blind*."

154. Defendant Polymeropoulos stated in the 11/15/13 Form 8-K, in pertinent part, that: "[w]e are now one step closer toward our goal of providing a treatment option that addresses the physiologic cause of this serious, debilitating orphan condition that impacts a majority of totally blind individuals."

155. The FDA officially approved Hetlioz in January 2014.

156. Notwithstanding that the NDA for Hetlioz acknowledged that it was to treat Non-24 in blind individuals, on January 31, 2014, the FDA sent Vanda a letter clarifying that Hetlioz had been approved for sale in the United States to treat Non-24 regardless of whether or not the patient was blind.

157. During the Relevant Period, the Individual Defendants continued to acknowledge that Non-24 rarely, if ever, occurs in sighted individuals, even as the Company aggressively marketed and promoted Hetlioz off-label to sighted individuals, as discussed herein.

158. For example, on March 7, 2017, defendant Kelly participated at the Cowen Health Care Conference and stated to Vanda's investors, in pertinent part, as follows:

> But first, some background on non-24 itself. This is a rare circadian rhythm disorder that impacts approximately 80,000 individuals in the US. *It occurs almost exclusively in the totally blind*, and these are blind individuals without light perception which, in turn, inhibits their ability to reset their circadian clock.

THE INDIVIDUAL DEFENDANTS KNEW ABOUT, OR RECKLESSLY DISREGARDED, THE OFF-LABEL PROMOTION SCHEME FOR HETLIOZ

159. Although Vanda repeatedly acknowledged that Non-24 rarely, if ever, occurs in sighted individuals, the Company focused its promotional efforts for Hetlioz during the Relevant Period in sighted individuals regardless of whether they had Non-24.

160. Even worse, Vanda's promotional efforts for Hetlioz were concentrated on psychiatrists, who focus on the diagnosis and treatment of mental health disorders, not blind patients,

let alone patients who may be experiencing any type of sleeping disorder, least of all Non-24. Instead, the Individual Defendants undertook a scheme to promote Hetlioz off-label.

161. According to Gardner and Bourgeois, during the November 2015 Meeting, the Fanapt 50 and the RBLs were instructed to ensure that Hetlioz was introduced to the psychiatrists that were being targeted for Fanapt.

162. According to Gardner, to pitch Hetlioz to psychiatrists, defendant Polymeropoulos instructed the RBLs to direct the sales representatives to ask the doctors "do you have any blind patients?" Regardless of the answer, the sales representatives were instructed to state that "Hetlioz is a drug that is effective in treating circadian rhythm disruption" and to leave the doctor with a Hetlioz sales packet.

163. Defendant Polymeropoulos told the RBLs that psychiatrists would understand that if Hetlioz treats circadian rhythm disruption in Non-24 that it could also treat non-blind patients with other sleep disorders caused by circadian rhythm disruption, such as shift work sleep disorder, jet lag, and insomnia.

164. According to Gardner and Bourgeois, this sales pitch was designed to, and in fact did, result in off-label prescriptions of Hetlioz.

165. According to Gardner and Bourgeois, at no point in time during either of their employments with Vanda did anyone discuss with them that a doctor can diagnose Non-24 or that blood and urine tests can be used to assist in a Non-24 diagnosis. To the contrary, Gardner and Bourgeois recount that Vanda informed them that there was no way to tell if someone had Non-24, which is why the drug could be used to treat any circadian rhythm disorder.

166. According to Bourgeois, if physicians would inquire about whether there was any way to test patients for Non-24, Vanda trained its representatives to respond by pivoting the

conversation to discussing that individuals with mental disorders were good candidates for Hetlioz because many of them have difficulty sleeping.

167. After the Fanapt 50 pitched Hetlioz to a psychiatrist, they were required to pass the account over to a Hetlioz sales representative, who would try to close the sale. Vanda referred to these as "pass-alongs." Vanda informed the Fanapt 50 that they would be held accountable for how many pass-alongs they provided to the Hetlioz sales team. According to Gardner, the number of pass-alongs a sales representative secured was documented in these representatives' company-issued laptops following every sales call.

168. According to Gardner, in May 2016, Ramirez held a meeting with the RBLs and reprimanded them because the Fanapt 50 were not producing enough pass-alongs. During the call, some of the RBLs stated that the psychiatrists that the Fanapt 50 were contacting did not have any blind patients. Ramirez responded that it was mandatory that the Fanapt 50 promote Hetlioz on every sales call.

169. According to Bourgeois, Vanda intended to promote Hetlioz off-label for conditions other than Non-24. Bourgeois recounts that sales representatives were trained to respond to a question from doctors asking if Hetlioz is only for blind patients by stating that if a patient does not have normal sleep habits, then they should use Hetlioz regardless of whether they are blind.

170. According to Bourgeois, some doctors would ask how they could tell if their patients had Non-24. Bourgeois recounts that Vanda trained its sales representatives to respond by telling the doctor that if their patient had tried other sleep aides and were still experiencing sleep issues, that they probably have Non-24.

171. According to Bourgeois, several sales representatives expressed concerns about selling Hetlioz to sighted patients and asked Vanda's senior management to see data that supported the efficacy of Hetlioz in sighted patients. Bourgeois recounts that Vanda's senior management responded that Non-24 occurs in blind patients but also those with mental conditions, so if a psychiatrist has patients who have trouble sleeping, and have tried Ambien and it did not work, that they should prescribe Hetlioz.

172. According to Bourgeois, Vanda's promotional materials for Hetlioz also demonstrated an intent to promote Hetlioz off-label because they did not focus on patients with Non-24. Instead, the call guidance sheets for Hetlioz instructed sales representatives to tell doctors that "Non-24 has been associated with traumatic brain injury and depressive and bipolar mood disorders. Blindness is also a risk factor."

173. In addition, according to Bourgeois, in early 2018 he was contacted by Arnold regarding his usage of the word "sleep" as opposed to "Non-24" in his sales representative reports for Hetlioz. Bourgeois recounts that Arnold told him that the word "sleep" needed to be removed from Hetlioz sales representative reports because defendant Polymeropoulos was concerned about being sued by the government. Bourgeois ultimately removed "sleep" from his Hetlioz sales representative reports.

174. According to Bourgeois, Arnold informed him that other RBLs were using the word "sleep" in their Hetlioz sales representative reports and that she had been raising the same concerns with them.

175. Further, according to Bourgeois, Hetlioz was being promoted off-label because certain sales representatives were able to obtain an out-sized number of prescriptions written for Hetlioz, while most struggled to achieve more than one or two prescriptions per fiscal quarter.

176. Bourgeois recounts that Scott Grontkowski ("Grontkowski"), a Vanda sales representative from Rockford, Illinois, from January 2017 to the present, had gotten doctors to write over 50 prescriptions for Hetlioz in a quarter, even though according to Bourgeois, none of these prescriptions were for blind patients.

177. In FY17, Vanda sold almost $90 million worth of Hetlioz. At Hetlioz's price of $148,000 per year (a price that had undoubtedly risen by 2017), this meant that Vanda had written approximately 608 prescriptions for Hetlioz during FY17. Assuming he only sold 50 prescriptions, Grontkowski accounted for approximately 8.2% of the Hetlioz prescriptions written in FY17.

178. According to Bourgeois, Grontkowski was asked by Vanda to present at the Company's 2018 national sales meeting (the "2018 Meeting") to demonstrate his pitch for selling Hetlioz. Griffin, Ramirez, and defendant Reverberi attended the 2018 Meeting, which took place in Washington, D.C.

179. Bourgeois recounts that Grontkowski's sales pitch during the 2018 Meeting contained nothing about Hetlioz's efficacy in treating Non-24. Instead, Bourgeois recounts that Grontkowski stated during the 2018 Meeting that Grontkowski tells doctors if they have patients who cannot sleep, they should prescribe them Hetlioz to get them sleeping right now.

180. During the early part of the Relevant Period, the Individual Defendants did not acknowledge that its Fanapt sales force was being used to promote Hetlioz to psychiatrists. That changed in July 2017, when Vanda announced it was beginning the "Hetlioz to Psychiatrists Initiative," which the Individual Defendants termed "HPI." According to the Individual Defendants, the HPI involved having Fanapt sales representatives call psychiatrists to promote Hetlioz.

181. According to Gardner and Bourgeois, however, even though the HPI was announced as beginning in July 2017, Vanda had been using Fanapt sales representatives to promote Hetlioz for years before the announcement, since at least November 2015.

182. The Aurelius Report publicly revealed for the first time, among other things, the Individual Defendants' off-label marketing scheme for both Fanapt and Hetlioz. As stated in the Aurelius Report issued on February 11, 2019, which was based, in part, on interviews with unnamed former Vanda employees and an unnamed sleep doctor, according to a former unnamed Vanda sales representative "[w]e were [internally] saying 'give it to everyone who doesn't sleep well.'" The unnamed sleep doctor in the Aurelius Report opined that "[Vanda is] prescribing [Hetlioz] off label and calling it's [sic] something it's not."

183. On this news, the trading price of Vanda's common stock declined $1.05 per share, or 5.51%.

TRADIPITANT WAS VANDA'S MOST IMPORTANT CLINICAL PIPELINE DRUG DURING THE RELEVANT PERIOD

184. Of the few drugs that Vanda had in clinical development during the Relevant Period, tradipitant was the most promising in terms of potentially obtaining FDA approval.

185. Indeed, according to defendant Polymeropoulos during a conference call held on November 7, 2017 for analysts and investors to discuss Vanda's financial results and performance for 3Q17 (the "11/7/17 Call"), "[t]radipitant [is] the most exciting clinical milestone for Vanda[.]"

186. For this reason, investors and analysts placed importance on tradipitant's prospects during the Relevant Period.

187. Tradipitant was being clinically tested by Vanda during the Relevant Period for two potential indications: (i) gastroparesis, a disorder that prevents the stomach from emptying food in a normal fashion; and (ii) atopic dermatitis, or eczema.

188. According to defendant Polymeropoulos, tradipitant's potential for treating gastroparesis presented a significant economic opportunity for Vanda. During a conference call with analysts and investors held on December 3, 2018 ("12/3/18 Conference Call") defendant Polymeropoulos stated, in pertinent part, that:

> Before going into more detail on the study results, I would like to provide an overview of the significant unmet medical need for gastroparesis patients.
>
> Gastroparesis is a serious chronic medical condition, characterized by delayed gastric emptying and associated with the symptoms of nausea, vomiting, bloating, fullness after meals, abdominal pain, along with significant impairment of social and occupational functioning.
>
> The estimated prevalence of gastroparesis in the U.S. is over 5 million people, many of whom remain undiagnosed.
>
> Gastroparesis affects mostly women, and it can be of various etiologies including diabetes mellitus and idiopathic causes.
>
> The only U.S. Food and Drug Administration approved treatment for gastroparesis is metoclopramide, approved in 1979, which due to its potential of severe side effects, carries a black box warning and has limitations of use of no more than 3 months.
>
> Patients are faced with limited therapeutic options and clinical guidelines recommend in addition to metoclopramide, the off-label use of different drugs including erythromycin, domperidone, which is not approved in the U.S., botulinum toxin injections, gastric simulators and a variety of surgical procedures in an effort to relieve, even temporarily, some of the symptoms of the disease.
>
> Gastroparesis treatment represents a significant unmet medical need as underscored by the testimonies of interested parties and advocacy organizations included the International Foundation for Gastrointestinal Disorders and Gastroparesis Patient Association for Cures and Treatments.

189. Tradipitant's potential for treating gastroparesis was a central focus of Vanda's Relevant Period clinical trial efforts for tradipitant.

190. Given the importance of tradipitant to Vanda's clinical pipeline, the Company spent the bulk of its direct project costs for its clinical trial drugs on tradipitant as compared to other drugs it had.

191. According to the Form 10-K with the SEC for FY17 (the "2017 Form 10-K"), Vanda spent $11.645 million on direct project costs for tradipitant during FY17 out of $15.997 million spent on direct project costs for its clinical trial drugs, or 72.7%.

192. According to the Form 10-Q for 1Q18 ("1Q18 Form 10-Q"), Vanda spent $2.277 million on direct project costs for tradipitant during 1Q18 out of $3.619 million spent on direct project costs for its clinical trial drugs, or 62.9%.

193. According to the Form 10-Q for 2Q18 ("2Q18 Form 10-Q"), Vanda spent $4.372 million on direct project costs for tradipitant during 2Q18 out of $5.974 million spent on direct project costs for its clinical trial drugs, or 73.2%.

194. According to the Form 10-Q for 3Q18 ("3Q18 Form 10-Q"), Vanda spent $5.113 million on direct project costs for tradipitant during 3Q18 out of $7.142 million spent on direct project costs for its clinical trial drugs, or 71.6%.

195. Accordingly, during the Relevant Period, Vanda's clinical trial efforts for tradipitant were of high importance such that knowledge of the efforts can reasonably be attributed to management and the Board.

VANDA ADMITS IN THE FDA LITIGATION ITS KNOWLEDGE, OR RECKLESS DISREGARD, BY MAY 2018 THAT A CLINICAL TRIAL HOLD WOULD BE PLACED ON CRITICAL TRADIPITANT STUDIES

196. On May 29, 2019, Vanda filed an amended complaint in the FDA Litigation (the "Vanda FDA Complaint"), which contained Vanda's allegations against the FDA regarding a clinical trial hold that has been placed on certain tradipitant studies that were highly material and important to Vanda's investors.

197. On July 10, 2019, Vanda filed a memorandum of law in support of its motion for summary judgment in the FDA Litigation (the "Vanda SJ Brief"). The Vanda SJ Brief contains citations to documents included in the Index of Administrative Records prepared by the FDA for the FDA Litigation.

198. According to the Vanda FDA Complaint, Vanda submitted its original protocol for VLY686-2301 ("Study 2301") to the FDA on August 17, 2016. Study 2301 was "a multicenter, randomized, double-blind placebo-controlled study of tradipitant for subjects diagnosed with gastroparesis."

199. According to the Vanda FDA Complaint, Study 2301 was initiated on November 22, 2016.

200. Study 2301 was a Phase II trial. According to the FDA, clinical trials are often conducted in three phases, with Phase III trials generally involving more patients and a longer duration than Phase II trials. This means that even if Study 2301 were successful, Vanda still needed to conduct a Phase III trial on gastroparesis for the FDA to approve tradipitant to treat gastroparesis.

201. According to the Vanda FDA Complaint, Vanda subsequently submitted several protocol amendments to the FDA with respect to the duration of Study 2301.

202. According to the Vanda FDA Complaint, on December 5, 2017, Vanda submitted protocol amendment #5, which, among other things, provided for Study 2301 to last for eight weeks, consisting of a four-week screening phase followed by a four-week evaluation phase.

203. According to the Vanda FDA Complaint, on April 10, 2018, Vanda submitted protocol amendment #6 to, among other things, extend Study 2301 to add a 52-week, open-label extension period. Effectively, protocol amendment #6 sought to greatly expand the duration of Study 2301.

204. According to the Vanda FDA Complaint, during a May 15, 2018, teleconference between the FDA and Vanda (the "5/15/18 Call"), the FDA informed Vanda that the Company could not extend Study 2301 to be a full year clinical trial unless Vanda completed a 9-month non-rodent toxicity study on tradipitant.

205. The FDA requires toxicity studies for drugs like tradipitant to ensure that the drug is safe for use in humans thus it was not surprising that the FDA would want tradipitant to be tested in animals for nine months before being used on humans in a one-year study.

206. According to the FDA, one of their roles during the clinical trial process is to protect volunteers who participate in such trials from unreasonable and significant risk. For this reason, the FDA has the power to place a clinical hold on a trial that exposes its participants to, among other things, unreasonable or significant risk.

207. According to the FDA, "[a] clinical hold is rare; instead, FDA often provides comments intended to improve the quality of a clinical trial." This is consistent with the FDA's mandate to allow "wide latitude in clinical trial design."

208. According to the Vanda SJ Brief, at all relevant times, the FDA "made clear that continued human trials beyond 3 months [for tradipitant] would not be allowed to proceed without a 9-month [toxicity] study[.]"

209. According to the Vanda FDA Complaint, during the 5/15/18 Call, the FDA informed Vanda that, if the nine-month non-rodent study was not conducted, the FDA would place a clinical hold on Study 2301 to prevent the 52-week extension study.

210. According to the Vanda SJ Brief, the FDA stated during the 5/15/18 Call that "'chronic toxicology studies in 2 species is a requirement, not a recommendation, prior to proceeding to long-term studies in humans.'"

211. Thus, as of the 5/15/18 Call, the Individual Defendants surely knew that, if they chose not to conduct the nine-month non-rodent study, a fully year clinical trial for tradipitant would not be approved by the FDA.

212. According to the Vanda SJ Brief, on May 18, 2018, the FDA concluded that "'a chronic toxicology study of 9 months duration will be needed'" and that tradipitant "trials beyond 3 months 'should be put on clinical hold until the chronic toxicity study in a non-rodent species is submitted for our review.'"

213. According to the Vanda FDA Complaint, to avoid a clinical hold being placed on Study 2301, Vanda submitted an amended protocol to the FDA on May 22, 2018, that, among other things, limited Study 2301 to no more than three months in duration.

214. According to the Vanda FDA Complaint, on May 24, 2018, the FDA approved the amended protocol and allowed Study 2301 to proceed for no longer than three months in duration without having to conduct the nine-month non-rodent toxicity study.

215. According to the Vanda SJ Brief, on August 1, 2018, Vanda filed a formal dispute resolution request contesting the FDA's determination that the nine-month non-rodent toxicity study was necessary in order to conduct a clinical trial for gastroparesis in excess of three months. According to the Vanda SJ Brief, the FDA responded to this request by sending Vanda a one-page letter stating that Vanda's formal dispute "was 'not accepted.'"

216. According to the Vanda FDA Complaint, on September 26, 2018, Vanda submitted a new clinical study protocol, Study 2302, to the FDA that was the same 52-week open-label extension study that Vanda proposed as protocol amendment #6 for Study 2301.

217. According to the Vanda FDA Complaint, as of November 2018, Vanda had not begun Study 2302.

218. On December 3, 2018, the Company issued a press release, which was also filed on Form 8-K, which announced positive results from Study 2301 (the "12/3/18 Form 8-K"). According to the 12/3/18 Form 8-K, and the conference call the Company held that same day to report the results from Study 2301, this Phase II study was successful but an additional, longer study that also had positive results was ultimately needed in order to obtain FDA approval for tradipitant to treat gastroparesis.

219. According to the Vanda FDA Complaint, on December 11, 2018, Vanda submitted a protocol amendment to Study 2301 that once again requested to add a 12-month open-label extension to Study 2301. According to the Vanda FDA Complaint, this proposed amendment to Study 2301 is similar to Study 2302.

220. According to the Vanda FDA Complaint, on December 19, 2018, the FDA informed Vanda by telephone that Study 2301 and 2302 had been placed on partial clinical holds because Vanda had not complied with the FDA's request – communicated to Vanda on the 5/15/18 Call — that the Company conduct a nine-month non-rodent toxicity to study to ensure that tradipitant is safe for long-term use in humans.

221. According to the Vanda FDA Complaint, on December 21, 2018, the FDA provided Vanda with a letter that contained a written explanation for the partial clinical trial holds placed on Study 2301 and Study 2302. According to the Vanda FDA Complaint, the FDA reiterated in its December 21, 2018 letter, in pertinent part, that "non-rodent toxicity studies of 9 months duration are required for the conduct of [Vanda's] proposed clinical investigations of 52 weeks (12 months) duration[.]"

222. According to the initial complaint filed by Vanda in the FDA Litigation on February 5, 2019, the FDA could not have been more clear that, at all relevant times in 2018, Vanda's failure

to conduct the nine-month non-rodent toxicity study would result in a clinical hold, with Vanda alleging, in pertinent part, that:

> *Throughout 2018, including in the Clinical Hold Letter and in Vanda's conversations with [the FDA], FDA made clear that, one way or another, Vanda would be obligated to conduct the nine-month study[.]*

223. According to the Vanda FDA Complaint, on December 21, 2018, Vanda requested a reconsideration of the partial clinical holds imposed by the FDA.

224. According to the Vanda FDA Complaint, on January 4, 2019, the FDA informed Vanda it was denying the Company's request for reconsideration.

225. The Individual Defendants did not tell investors about the threat to Vanda's clinical testing regime for tradipitant caused by the Company's refusal to conduct a routine safety test on tradipitant until after the market closed on February 5, 2019, when, to the surprise of investors and analysts, Vanda issued a press release announcing that it had initiated the FDA Litigation to, among other things, lift the partial clinical holds. On this news, the trading price of Vanda's common stock declined $5.00 per share, or 19.95%.

226. Analysts were deeply concerned by the Individual Defendants' decision to sue the FDA, and its related refusal to conduct a routine safety test for tradipitant. For example, in a February 6, 2019 report on Vanda, analyst Ester Rajavelu of Oppenheimer & Co. stated:

> VNDA's announcement that it is pursuing legal action against the FDA due to a partial clinical hold restricting tradipitant dosing to 3 months ***comes as a surprise to us***. The FDA is requesting tox data from a nine month non-rodent study to allow longterm dosing in clinical trials. While management acknowledges this would be a low cost study it believes FDA's requirement to be unethical due to the euthanizing of dogs (we note other non-human mammals could also be used). While our valuation does not include tradipitant revenues, we view a lawsuit as a non-optimal strategy . . .

* * *

> *We note the FDA's request for nine-month tox data from non-human mammals is not unusual given gastroparesis and atopic dermatitis are chronic conditions requiring long-term therapy*.

227. In addition, in a February 6, 2019 report on Vanda, analyst Derek Archila of Stifel Nicolaus stated:

> We believe VNDA's decision to sue the FDA for what it feels are unnecessary animal studies' and due to the company's current refusal to run these studies having resulted in a partial clinical hold on tradipitant, *this will certainly raise questions among investors about the clinical timelines for this program and whether or not management is really focused on creating value for its shareholders*.

228. Likewise, a February 12, 2019 *Washington Business Journal* report on Vanda, which included quotes from an interview conducted by the *Washington Business Journal* with defendant Polymeropoulos that day, stated:

> While the clinical hold doesn't affect Vanda's timing for filing an application for FDA approval at this point, it could delay progress if it's not resolved in the next few months, Polymeropoulos said. That's because the hold isn't on ongoing studies - Vanda plans to start a new phase 3 study in gastroparesis in the next few months. *But it would postpone proposed studies to treat patients for longer than three months, a typical requirement for market authorization. "So if we were not allowed to collect this information at the time of filing, we're not going to have sufficient information to seek approval," Polymeropoulos said.*

229. Vanda's refusal to conduct the necessary safety testing for tradipitant during the Relevant Period rendered false and misleading the repeated statements made by the Individual Defendants during the Relevant Period regarding the progress of Study 2301, tradipitant's future prospects given the positive results of Study 2301, and other representations in Vanda's SEC filings regarding tradipitant. The Individual Defendants were informed during the 5/15/18 Call that the FDA would not approve an extended study of tradipitant if Vanda did not conduct the required safety testing, yet the Individual Defendants knowingly failed to include this information when communicating to Company investors, thereby rendering the statements made materially false and misleading.

THE INDIVIDUAL DEFENDANTS CAUSED THE COMPANY TO ISSUE MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE RELEVANT PERIOD

230. During the Relevant Period, the Individual Defendants made materially false and misleading statements, and otherwise violated an obligation to disclose material information, concerning: (i) the Company's scheme to promote Fanapt off-label; (ii) the Company's scheme to promote Hetlioz off-label; (iii) Vanda's decision to forgo a routine safety study that the Company knew would result in a clinical trial hold for tradipitant; and (iv) known uncertainties, events, trends and material risks associated with Vanda's operations.

231. The Relevant Period begins on November 4, 2015. The previous day, November 3, the Company held a conference call for analysts and investors (the "11/3/15 Call") after the market closed to discuss Vanda's financial results and performance for the third fiscal quarter of 2015 ("3Q15"). During the 11/3/15 Call, Gibbs stated:

> And when we drilled down at the individual territory level we were able to measure the promotional response based upon reach and frequency and based upon the early data it provided a strong signal confirming the promotional sensitivity of Fanapt. Based upon those data, *we have decided to expand the Fanapt 12 to Fanapt 50 where we're going to be populating 50 of the most productive territories creating a competitive share of voice which we think we will be able to replicate the results that we saw within the Fanapt 12 and stabilize the Fanapt business exiting 2015*.

232. The statements made in ¶231 were materially false and misleading when made because Vanda had not "decided to expand the Fanapt 12 to Fanapt 50" to "stabilize the Fanapt business existing 2015." Instead, at all relevant times before and during the Relevant Period, Vanda was engaged in an off-label promotion scheme for Fanapt, and the expansion from the Fanapt 12 to the Fanapt 50 was designed to increase the scope and extent of that scheme.

233. In addition, by speaking about the topic of expanding the sales force for Fanapt, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda's expansion from the Fanapt 12 to the Fanapt 50 was designed to

increase the scope and extent of the Company's off-label promotion scheme for Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Individual Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period rendered this statement materially false and misleading.

234. On November 4, 2015, Vanda filed a Form 10-Q for 3Q15 (the "3Q15 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q15 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®.*"

235. By speaking about the topic of the importance of successfully commercializing Fanapt, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda was using an off-label promotion scheme to commercialize Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period rendered this statement materially false and misleading.

236. On November 19, 2015, defendant Polymeropoulos participated at the Jefferies Autumn Global Healthcare Conference (the "11/19/15 Conference") to discuss the Company and its business. During the 11/19/15 Conference, defendant Polymeropoulos stated:

> Some of the side effects are — include metabolic weight, movement disorders, *but there is one that Fanapt/iloperidone can differentiate itself, and that is akathisia*. Akathisia is a state of inner restlessness often leading to suicidal thoughts and many times completed suicide. And that is not a symptom of schizophrenia. It is a side effect of the drugs to treat schizophrenia. Unfortunately, many of these new drugs that are offered quite a bit to patients have a mechanism of action that develops the

> side effect of akathisia. *Fanapt does not have it. And on the US label, you can read that the akathisia rates for Fanapt are equal to placebo. So we believe there is a place for Fanapt in the schizophrenia market and the opportunity can be significant*.
>
> * * *
>
> We have not put commercial effort behind [Fanapt] yet. Some effort began as a pilot of 12 account managers in August. *And now with encouraging results in the pilot, we are moving to building a 50-person sales force in the US*.

237. By speaking about the topic of Fanapt's relatively low rate of akathisia in the context of treating schizophrenia, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda was using Fanapt's potential in reducing akathisia as a central part of its off-label promotion scheme for Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Individual Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period rendered this statement materially false and misleading.

238. Moreover, defendant Polymeropoulos' discussion of building "a 50-person sales force in the US" above in ¶236 was materially false and misleading when made for the reasons set forth in ¶¶232-233.

239. On February 10, 2016, the Company held a conference call for analysts and investors (the "2/10/16 Call") to discuss Vanda's financial results and performance for the fourth fiscal quarter of 2015 ("4Q15") and FY15. During the 2/10/16 Call, defendant Polymeropoulos stated:

> *In late Q4, we completed the launch of a 50-person Fanapt-dedicated sales force, which is promoting Fanapt primarily to psychiatrists across the U.S.* Our goal is to stabilize the unit demand for Fanapt with this effort.

240. The statements referenced above in ¶239 were materially false and misleading for the reasons set forth in ¶¶232-233.

241. On February 12, 2016, Vanda filed its annual report on Form 10-K with the SEC for FY15 (the "2015 Form 10-K"), which was signed by defendants Polymeropoulos, Kelly, Watkins, Bate, Cola, Dugan, and Milano. The 2015 Form 10-K discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®. "*

242. The statement referenced above in ¶241 was materially false and misleading for the reasons set forth in ¶235.

243. The 2015 Form 10-K also discusses the notion that Vanda could fail to comply with applicable laws and regulations regarding selling and promoting Fanapt, stating:

> *Failure to comply with government regulations regarding the sale and marketing of our products could harm our business*.

244. The statement in ¶243 was materially false and misleading because it failed to disclose that it was not merely possible that failing to comply with applicable laws and regulations regarding selling and marketing Fanapt could disrupt the Company's business and financial performance; this risk had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

245. On May 4, 2016, the Company held a conference call for analysts and investors (the "5/4/16 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2016 ("1Q16"). During the 5/4/16 Call, defendant Polymeropoulos stated:

> In the 50 territories in which we began promoting Fanapt through our sales force, we observed a significantly lower rate of demand decline as compared to non-promoted territories. As a reminder, *we increased our field force from a 12-person pilot to a 50-person team in December of 2015*.

246. The statement referenced above in ¶245 was materially false and misleading for the reasons set forth in ¶¶232-233.

247. On May 5, 2016, Vanda filed a Form 10-Q for 1Q16 (the "1Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt*®"

248. The statement referenced above in ¶247 was materially false and misleading for the reasons set forth in ¶235.

249. The 1Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015*.

250. The statement referenced in ¶249 above was materially false and misleading when made because, as set forth in ¶244, the risk described in the 2015 Form 10-K regarding the potential harm to Vanda from failing to comply with applicable laws and regulations in selling and marketing Fanapt was not merely prospective; it had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

251. On June 9, 2016, defendant Polymeropoulos participated in the 6/9/16 Conference to discuss the Company and its business. During the 6/9/16 Conference, defendant Polymeropoulos stated:

> And for those individuals who develop this restlessness [akathisia] when taking other antipsychotics, *we are recommending Fanapt as a second-line treatment*. As many people know, there are quite a few antipsychotics on the market and it is incredibly important to best position your drug. This is a promotionally sensitive class.

> And so, with that said, we initiated our promotion in April of last year initially with a pilot of about 12 reps to understand the messaging, the promotional sensitivity. *We expanded that field force from 12 to 50 at the end of last year*, and you can see the results that we have had since bringing Fanapt back in house.

252. The statement referenced above in ¶251 that "we are recommending Fanapt as a second-line treatment [for akathisia]" was materially false and misleading because by speaking about the topic of Fanapt's status as a second line treatment, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda was promoting and marketing Fanapt as a first line treatment, meaning off-label, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Individual Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period rendered this statement materially false and misleading.

253. The statement referenced above in ¶251 that "[w]e expanded that field force from 12 to 50 at the end of last year" was materially false and misleading for the reasons set forth in ¶¶232-233.

254. On June 21, 2016, defendant Polymeropoulos participated in the JMP Securities Life Sciences Conference (the "6/21/16 Conference") to discuss the Company and its business. During the 6/21/16 Conference, defendant Polymeropoulos stated:

> *We put 12 sales reps in the field last August, supplemented by another 38 in December*. So now the full 50 have been on board for the first and now second quarter. So, what we see is what you described, Jason: the beginnings of stabilizing that decline. Still, we see some overall decline around the country. We did an analysis in the first quarter, where the territory supported by 50 reps are significantly outperforming white space. So, we know they are doing something good. We certainly wanted to be supported and do more, stabilize the decline and eventually return to growth.

* * *

> *We are working on differentiation with our sales force*. We know from the US label that the rate of akathisia, a very significant side effect by some antipsychotics, is similar to placebo. *And physicians now very quickly are becoming aware of that as well*.

255. The statement referenced above in ¶254 that "[w]e put 12 sales reps in the field last August, supplemented by another 38 in December" was materially false and misleading for the reasons set forth in ¶¶232-233.

256. The statements referenced above in ¶254 that "[w]e are working on differentiation with our sales force" and "physicians now very quickly are becoming aware of that as well" were materially false and misleading for the reasons set forth in ¶237.

257. On July 27, 2016, the Company held a conference call for analysts and investors (the "7/27/16 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2016 ("2Q16"). During the 7/27/16 Call, defendant Polymeropoulos stated:

> And just to address, now, specifically your question, *we're very excited about the early signs of effectiveness of our 50-people sales force*, in that, in the territories of the 50, we see based on IMS and Symphony Health a decline of less than 1% in the promoted territories. And that compares with a continuous decline in the white space. And just to give you an order of magnitude, our 50 territories attempt to address about 70% of the prescribing universe. So, the white space is 30%. And with that, *the lesson learned is that promotion does work, and it is received well. Our sales force is doing a great job. We'll continue to try to improve our message and the effectiveness of the sales force.*

258. The statements referenced above in ¶257 that "we're very excited about the early signs of effectiveness of our 50-people sales force," "our sales force is doing a great job," and "[w]e'll continue to try to improve our message and the effectiveness of the sales force" were materially false and misleading for the reasons set forth in ¶¶232-233.

259. On July 28, 2016, Vanda filed a Form 10-Q for 2Q16 (the "2Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate*

meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®"

260. The statement referenced above in ¶259 was materially false and misleading for the reasons set forth in ¶235.

261. The 2Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015.*

262. The statement referenced above in ¶261 was materially false and misleading for the reasons set forth in ¶244.

263. On November 2, 2016, the Company held a conference call for analysts and investors (the "11/2/16 Call") to discuss Vanda's financial results and performance for the third fiscal quarter of 2016 ("3Q16"). During the 11/2/16 Call, in response to an analyst's question about how the clinical profile of Fanapt fits into other possible indications for Fanapt being pursued by the Company, defendant Polymeropoulos stated:

> Just before I answer this question, just to remind everybody that Fanapt is approved for the indication of schizophrenia in adults in the US. I refer everybody for a full discussion of efficacy and safety to www.fanapt.com.
>
> * * *
>
> So we believe *that Fanapt, in patients with schizophrenia, will be a drug that will be used once patients switch from another medication*, primarily because of tolerability; and specifically, that specific schizophrenia patient that needs to switch and has experienced drug-induced akathisia on another drug may be actually a very well-suited patient for Fanapt.
>
> * * *
>
> *We, of course, are always interested in pediatric applications.* We know that two other agents in the antipsychotic space have been developed for certain symptoms of

> irritability in children with autism, and that is an indication part of the long-term planning for a pediatric indication.

264. The statement referenced above in ¶263 that "Fanapt, in patients with schizophrenia, will be a drug that will be used once patients switch from another medication" was materially false and misleading for the reasons set forth in ¶¶235, 237, 252.

265. The statements referenced above in ¶263 that "[w]e, of course, are always interested in pediatric applications [for Fanapt," Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that the Company's off-label promotion scheme for Fanapt involved marketing it to pediatric patients, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period rendered this statement materially false and misleading.

266. On November 3, 2016, Vanda filed a Form 10-Q for 3Q16 (the "3Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt*®"

267. The statement referenced above in ¶266 was materially false and misleading for the reasons set forth in ¶235.

268. The 3Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015*.

269. The statement referenced above in ¶268 was materially false and misleading for the reasons set forth in ¶244.

270. On February 15, 2017, the Company held a conference call for analysts and investors (the "2/15/17 Call") to discuss Vanda's financial results and performance for the fourth fiscal quarter of 2016 ("4Q16") and FY16. During the 2/15/17 Call, defendant Polymeropoulos stated:

> So as we had previously communicated, *the plan for this quarter is to expand the sales force from around 50 sales reps last year to about 120, increasing, therefore, both reach and ability of call frequency*. And we believe that the new sales force will be trained and ready to detail physicians by the end of this quarter

271. The statement referenced above in ¶270 that "the plan for this quarter is to expand the sales force from around 50 sales reps last year to about 120, increasing, therefore, both reach and ability of call frequency" was materially false and misleading for the reasons set forth in ¶¶232-233.

272. On February 17, 2017, Vanda filed its annual report on Form 10-K with the SEC for FY16 (the "2016 Form 10-K"), which was signed by defendants Polymeropoulos, Kelly, Watkins, Bate, Cola, Dugan, and Milano. The 2016 Form 10-K discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*"

273. The statement referenced above in ¶272 was materially false and misleading for the reasons set forth in ¶235.

274. The 2016 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and marketing Fanapt was merely speculative, stating:

> *Failure to comply with government regulations regarding the sale and marketing of our products could harm our business.*

275. The statement referenced above in ¶274 was materially false and misleading for the reasons set forth in ¶244.

276. On March 21, 2017, Polymeropoulos participated in the 3/21/17 Conference to discuss the Company and its business. During the 3/21/17 Conference, Polymeropoulos stated: "*Fanapt is considered in the US a second line treatment for schizophrenia*."

277. The statement referenced above in ¶276 was materially false and misleading for the reasons set forth in ¶252.

278. On May 2, 2017, the Company held a conference call for analysts and investors (the "5/2/17 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2017 ("1Q17"). During the 5/2/17 Call, defendant Reverberi stated:

> During the first quarter of 2017, we successfully completed the expansion of the Fanapt U.S. field sales team, and *the full team is now in the field promoting the benefits of Fanapt for adult schizophrenia patients with a significant increase in frequency to our target physicians audience*.

279. The statement referenced above in ¶278 was materially false and misleading for the reasons set forth in ¶¶232-233.

280. On May 3, 2017, Vanda filed a Form 10-Q for 1Q17 (the "1Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*"

281. The statement referenced above in ¶280 was materially false and misleading for the reasons set forth in ¶235.

282. The 1Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016.*

283. The statement referenced above in ¶282 was materially false and misleading for the reasons set forth in ¶244.

284. On August 2, 2017, the Company held a conference call for analysts and investors (the "8/2/17 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2017 ("2Q17"). During the 8/2/17 Call, defendant Polymeropoulos stated:

> After successfully completing the expansion of our Fanapt field sales team in the first quarter of 2017, *the full team has started promoting the benefits of Fanapt for adult schizophrenia patients with an expanded reach and frequency.*

285. The statement referenced above in ¶284 was materially false and misleading for the reasons set forth in ¶¶232-233, 237, 254, 265.

286. On August 3, 2017, Vanda filed a Form 10-Q for 2Q17 (the "2Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*"

287. The statement referenced above in ¶286 was materially false and misleading for the reasons set forth in ¶235.

288. The 2Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016.*

289. The statement referenced above in ¶288 was materially false and misleading for the reasons set forth in ¶244.

290. On September 13, 2017, defendant Kelly participated at the Morgan Stanley Healthcare Conference (the "9/13/17 Conference") to discuss the Company and its business. During the 9/13/17 Conference, defendant Kelly stated:

> But as we have put more effort behind the product, including what we just did right now, we are now initially seeing the slowing of the decline in what appears to be the degree of stabilization, what we're looking for is growth. *And it's our expectation that the reps we have put on board are going to have the ability to return Fanapt back to growth*.

291. The statement referenced above in ¶290 that "it's our expectation that the reps we have put on board are going to have the ability to return Fanapt back to growth" was materially false and misleading for the reasons set forth in ¶¶232-233, 237, 254, 265.

292. On November 8, 2017, Vanda filed a Form 10-Q for the third fiscal quarter of 2017 ("3Q17") (the "3Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*"

293. The statement referenced above in ¶292 was materially false and misleading for the reasons set forth in ¶235.

294. The 3Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016*.

295. The statement referenced above in ¶294 was materially false and misleading for the reasons set forth in ¶244.

296. On February 15, 2018, Vanda filed its annual report on Form 10-K with the SEC for FY17, the 2017 Form 10-K, which was signed by defendants Polymeropoulos, Kelly, Watkins, Bate, Cola, Dugan, and Milano. The 2017 Form 10-K discusses the importance to Vanda of successfully commercializing Fanapt, and stated: *"Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt® . . ."*

297. The statement referenced above in ¶296 was materially false and misleading for the reasons set forth in ¶235.

298. The 2017 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and promoting Fanapt was merely speculative, stating:

> *Failure to comply with government regulations regarding the sale and marketing of our products could harm our business.*

299. The statement referenced above in ¶298 was materially false and misleading for the reasons set forth in ¶244.

300. On May 2, 2018, the Company held a conference call for analysts and investors (the "5/2/18 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2018 ("1Q18"). During the 5/2/18 Call, defendant Polymeropoulos stated:

> *Our sales team continues making progress in introducing Fanapt as an additional option in treating adult patients with schizophrenia.*

301. The statement referenced above in ¶300 was materially false and misleading for the reasons set forth in ¶¶232-233, 239, 252, 265.

302. On May 2, 2018, Vanda filed a Form 10-Q for 1Q18 (the "1Q18 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q18 Form 10-Q discusses the

importance to Vanda of successfully commercializing Fanapt, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt*®"

303. The statement referenced above in ¶302 was materially false and misleading for the reasons set forth in ¶235.

304. The 1Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

305. The statement referenced above in ¶304 was materially false and misleading for the reasons set forth in ¶244.

306. On August 1, 2018, the Company held a conference call for analysts and investors (the "8/1/18 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2018 ("2Q18"). During the 8/1/18 Call, defendant Polymeropoulos stated:

> I also want to remind that in June, we undertook a reorganization of the Fanapt sales force that promote HPI, and that was a very significant reorganization. And we're in the midst of hiring in full the sales force back up to a number of 115 after we changed about 35-or-so sales representatives. So we do expect that this reorganization will affect the production of new scripts during that reorganization, but we do not expect the reorganization to affect the overall performance of the third quarter or beyond. *And we believe that this will strengthen, actually, our presence in the psychiatrist office in the promotion of both Fanapt and HETLIOZ.*

307. The statement referenced above in ¶306 that "we believe that this will strengthen, actually, our presence in the psychiatrist office in the promotion of both Fanapt and Hetlioz" was materially false and misleading for the reasons set forth in ¶¶232-233, 237, 252, 265.

308. On August 2, 2018, Vanda filed a Form 10-Q for 2Q18 (the "2Q18 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q18 Form 10-Q discusses the

importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt*®"

309. The statement referenced above in ¶308 was materially false and misleading for the reasons set forth in ¶235.

310. The 2Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

311. The statement referenced above in ¶310 was materially false and misleading for the reasons set forth in ¶244.

312. On November 7, 2018, Vanda filed the 3Q18 Form 10-Q, which was signed by defendants Polymeropoulos and Kelly. The 3Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: *"Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt*®"

313. The statement referenced above in ¶312 was materially false and misleading for the reasons set forth in ¶235.

314. The 3Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

315. The statement referenced above in ¶314 was materially false and misleading for the reasons set forth in ¶244.

THE FALSE AND MISLEADING HETLIOZ MISSTATEMENTS AND OMISSIONS

316. The 3Q15 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

317. By speaking about the topic of the importance of successfully commercializing Hetlioz, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda was using an off-label promotion scheme to commercialize Hetlioz, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Individual Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Hetlioz during the Relevant Period rendered this statement materially false and misleading.

318. The 2015 Form 10-K discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

319. The statement referenced above in ¶318 was materially false and misleading for the reasons set forth in ¶317.

320. The 2015 Form 10-K also discusses the notion that Vanda could fail to comply with applicable laws and regulations regarding selling and promoting Hetlioz, stating:

> *Failure to comply with government regulations regarding the sale and marketing of our products could harm our business*.

321. The statement in ¶320 was materially false and misleading because it failed to disclose that it was not merely possible that failing to comply with applicable laws and regulations regarding selling and marketing Hetlioz could disrupt the Company's business and financial

performance; this risk had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Hetlioz.

322. The 1Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

323. The statement referenced above in ¶322 was materially false and misleading for the reasons set forth in ¶317.

324. The 1Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015.*

325. The statement referenced in ¶324 above was materially false and misleading when made because, as set forth in ¶320, the risk described in the 2015 Form 10-K regarding the potential harm to Vanda from failing to comply with applicable laws and regulations regarding selling and promoting Hetlioz was not merely prospective; it had materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Hetlioz.

326. The 2Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

327. The statement referenced above in ¶326 was materially false and misleading for the reasons set forth in ¶317.

328. The 2Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015.*

329. The statement referenced above in ¶328 was materially false and misleading for the reasons set forth in ¶321.

330. The 3Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

331. The statement referenced above in ¶330 was materially false and misleading for the reasons set forth in ¶317.

332. The 3Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015.*

333. The statement referenced above in ¶332 was materially false and misleading for the reasons set forth in ¶321.

334. During the 2/15/17 Call, defendant Polymeropoulos stated:

> On HETLIOZ, our US commercial business is in its third year and continues to add new patients. *Our HETLIOZ team is focused on driving growth by creating awareness about non-24 and assisting patients to learn more about treatment options*.

335. By speaking about the topic of driving growth for Hetlioz, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda was using an off-label promotion scheme to drive growth for Hetlioz, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Individual Defendants' failure to adequately disclose an accurate portrayal of the

Company's efforts to market and sell Hetlioz during the Relevant Period rendered this statement materially false and misleading.

336. The 2016 Form 10-K discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

337. The statement referenced above in ¶336 was materially false and misleading for the reasons set forth in ¶317.

338. The 2016 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and promoting Hetlioz was merely speculative, stating:

> *Failure to comply with government regulations regarding the sale and marketing of our products could harm our business*.

339. The statement referenced above in ¶338 was materially false and misleading for the reasons set forth in ¶321.

340. During the 5/2/17 Call, defendant Reverberi stated:

> *The fundamentals of our HETLIOZ business remains strong*, as we consistently add new patients on therapy and are seeing early signs of improved persistency associated with the recent change to our specialty pharmacy network.

341. The statement referenced above in ¶340 that the "fundamentals of our Hetlioz business remains strong" was materially false and misleading for the reasons set forth in ¶335.

342. The 1Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

343. The statement referenced above in ¶342 was materially false and misleading for the reasons set forth in ¶317.

344. The 1Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016.*

345. The statement referenced above in ¶344 was materially false and misleading for the reasons set forth in ¶321.

346. During the 8/2/17 Call, defendant Polymeropoulos stated:

> *[I]n July, the Fanapt US field force team began promoting HETLIOZ to psychiatrists.* We're confident that this will represent a great opportunity to both expand the number of Non-24 patients who can benefit from HETLIOZ and reinforce the partnership with the psychiatrists by bringing solutions to patients with Non-24.

347. By speaking about Vanda's implementation of the HPI, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda had been marketing Hetlioz to psychiatrists since at least November 2015 and that such efforts centered on the off-label marketing of Hetlioz, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Individual Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Hetlioz during the Relevant Period rendered this statement materially false and misleading.

348. The 2Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

349. The statement referenced above in ¶348 was materially false and misleading for the reasons set forth in ¶317.

350. The 2Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated, in pertinent part, that:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016.*

351. The statement referenced above in ¶350 was materially false and misleading for the reasons set forth in ¶321.

352. On November 7, 2017, the Company held a conference call for analysts and investors (the "11/7/17 Call") to discuss Vanda's financial results and performance for 3Q17. During the 11/7/17 Call, defendant Polymeropoulos stated, in pertinent part, that:

> *So we did have experience before with sighted patients with Non-24 that have spontaneously come into the program.* And what we've seen in the past is that payers block more scripts that come out of sighted Non-24 patients than blind. Of course, we do not agree with that attitude; but nonetheless, it is a fact.

353. The statement referenced above in ¶352 that "we did have experience before with sighted patients with Non-24 that have spontaneously come into the program" was materially false and misleading for the reasons set forth in ¶347.

354. The 3Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

355. The statement referenced above in ¶354 was materially false and misleading for the reasons set forth in ¶317.

356. The 3Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016.*

357. The statement referenced above in ¶356 was materially false and misleading for the reasons set forth in ¶321.

358. On February 14, 2018, the Company held a conference call for analysts and investors (the "2/14/18 Call") to discuss Vanda's financial results and performance for the fourth fiscal quarter of 2017 ("4Q17") and FY17. During the 2/14/18 Call, defendant Polymeropoulos stated:

> We fully launched HPI with a full sales force promoting to psychiatrists beginning of October of 2017. So in this 3 months, over the last quarter, we saw a significant increase of the total scripts per month, which have more than doubled as compared to the monthly scripts seen before with the program which was based primarily on the Patient Directed Physician program, the PDP. *Just to clarify, Jason, in the past, some of the scripts were coming from sighted people as well. The difference is that in the HPI initiative, most of the patients are sighted.*

359. The statements referenced above in ¶358 that "in the past, some of the scripts were coming from sighted people as well" and the "difference is that in the HPI initiative, most of the patients are sighted" were materially false and misleading for the reasons set forth in ¶347.

360. The 2017 Form 10-K discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

361. The statement referenced above in ¶360 was materially false and misleading for the reasons set forth in ¶317.

362. The 2017 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and promoting Fanapt was merely speculative, stating:

> *Failure to comply with government regulations regarding the sale and marketing of our products could harm our business.*

363. The statement referenced above in ¶362 was materially false and misleading for the reasons set forth in ¶321.

364. During the 5/2/18 Call, defendant Polymeropoulos stated:

> *The HETLIOZ to Psychiatry Initiative, which was launched late last year, continues to drive an acceleration in new patient demand.* In the first quarter of 2018, we achieved a new all-time high number of new HETLIOZ intakes, these are the prescriptions and patient starts, as well as a new all-time high number of patients on therapy. *The positive response from the psychiatric community is a confirmation of the significant unmet medical need for patients with Non-24.*

365. The statements referenced above in ¶364 that "[HPI] continues to drive an acceleration in new patient demand" and the "positive response from the psychiatric community is a confirmation of the significant unmet medical need for patients with Non-24" were materially false and misleading for the reasons set forth in ¶347.

366. The 1Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

367. The statement referenced above in ¶366 was materially false and misleading for the reasons set forth in ¶317.

368. The 1Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

369. The statement referenced above in ¶368 was materially false and misleading for the reasons set forth in ¶321.

370. On May 9, 2018, defendant Kelly participated in the Deutsche Bank Healthcare Conference (the "5/9/18 Conference") to discuss the Company and its business. During the 5/9/18 Conference, defendant Kelly stated:

> In the U.S., the indication is Non-24 irrespective of vision status. And this is of importance because most recently in the U.S., *we launched an initiative, HETLIOZ to psychiatry initiative, where individuals with psychiatric comorbidities, many of whom may be sighted, have also begun to benefit from HETLIOZ. And of course, it's all within our U.S.-approved label.*

371. The statements referenced above in ¶370 that "many of whom may sighted, have also begun to benefit from Hetlioz" and "of course, it's all within our U.S.-approved label" were materially false and misleading for the reasons set forth in ¶347.

372. The 2Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

373. The statement referenced above in ¶372 was materially false and misleading for the reasons set forth in ¶317.

374. The 2Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

375. The statement referenced above in ¶374 was materially false and misleading for the reasons set forth in ¶321.

376. On September 12, 2018, defendant Kelly participated in the Morgan Stanley Healthcare Conference (the "9/12/18 Conference") to discuss the Company and its business. During the 9/12/18 Conference, defendant Kelly stated:

> And I'd say that this core blind business has been a great methodical growth story. But something changed last year in the fourth quarter. And what changed was a new initiative where we began targeting sighted individuals with psychiatric comorbidities who had Non-24. And what start us down this path was the work we were doing with Fanapt or atypical antipsychotic, where we're calling on 10,000 psychiatrists. *We decided after expanding our Fanapt field force last year to introduce HETLIOZ to that group, and the response has been incredible*. We saw a more than doubling of our scripts, and we shared with investors, both in the first quarter, second quarter, that we had all-time highs of both scripts and new patient starts, and it's being driven, the majority of it, by this sighted strategy. And so fairly unusual to have a product 5 years in that is continuing its core methodical growth and then add on top of it a new diversified approach to grow in the business.
>
> * * *
>
> And when we developed HETLIOZ for Non-24, our focus was on totally blind individuals, these individuals who lost that light perception, along with it, lost what is considered to be the standard mechanism to reset your body clock every day.

377. The statement referenced above in ¶376 that "[w]e decided after expanding our Fanapt field force last year to introduce Hetlioz to that group, and the response has been incredible" was materially false and misleading for the reasons set forth in ¶347.

378. On November 7, 2018, the Company held a conference call for analysts and investors (the "11/7/18 Call") to discuss Vanda's financial results and performance for 3Q18. During the 11/7/18 Call, defendant Polymeropoulos stated:

> HPI now is a year old, the program, and *what is impressive is the significant, continuous new demand, new scripts written by psychiatrists in the HPI initiative*. While Jim is correct that the PDP part of the business, which is mostly blind individuals, these are people we have opted into the database, continues to be a big driver and source. However, in new demand, and that is -- the definition of demand here is new scripts written, HPI continues to significantly outstrip the demand of PDP. So with that, one would have expected to actually saw even bigger growth than the 34%, which is nonetheless impressive. So why we have not seen even bigger growth? The HPI business, as we characterized before, has created a demand 2 to 3x higher than the PDP. However, the resistance by insurers on filling out the scripts, although it is the only indication and there is no other drug available for these patients, continues to be strong. We're working with our patients, we're working with the doctors to impress upon these insurers that this drug is necessary. We're making a lot of progress. But if we were to match the demand generated with fill, of course, these numbers would have been much, much bigger.

379. The statement referenced above in ¶378 that "what is impressive is the significant, continuous new demand, new scripts written by psychiatrists in the HPI initiative" was materially false and misleading for the reasons set forth in ¶347.

380. The 3Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated: "*Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*"

381. The statement referenced above in ¶380 was materially false and misleading for the reasons set forth in ¶317.

382. The 3Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

383. The statement referenced above in ¶382 was materially false and misleading for the reasons set forth in ¶321.

THE FALSE AND MISLEADING TRADIPITANT MISSTATEMENTS AND OMISSIONS

384. On August 1, 2018, the Company issued a press release, which was also filed on Form 8-K, that provided Vanda's 2Q18 financial results and performance to analysts and investors (the "8/1/18 Form 8-K"). The 8/1/18 Form 8-K stated:

> *A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected by the end of 2018.*

385. By speaking about the status of the 2301 Study, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda knew its unwillingness to conduct a routine non-rodent study to ensure tradipitant's safety for humans meant that the FDA would impose a clinical hold on a necessary extension of the 2301

Study, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Individual Defendants' failure to adequately disclose an accurate portrayal of tradipitant clinical trials during the Relevant Period rendered this statement materially false and misleading.

386. During the 8/1/18 Call, defendant Polymeropoulos stated:

> The recruitment efforts in the tradipitant gastroparesis clinical study are now working. We can now report that as of today, 110 patients have been randomized in the study. With a number of patients in screening, *we're now on target to randomize approximately 150 patients and expect to report results by year-end*.

387. The statement referenced above in ¶386 was materially false and misleading for the reasons set forth in ¶385.

388. The 2Q18 Form 10-Q stated:

> *A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected by the end of 2018.*

389. The statements referenced above in ¶388 were materially false and misleading for the reasons set forth in ¶385.

390. The 2017 Form 10-K contained a prospective risk warning pertaining to clinical trial results. The 2017 Form 10-K states:

> In the U.S., the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, as amended, and implements regulations. *If we fail to comply with the applicable requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include* the FDA's refusal to approve pending applications, withdrawals of approvals, *clinical holds*, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any such sanction could have a material adverse effect on our business.

391. The 2Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

392. The statement referenced above in ¶391 from the 2Q18 Form 10-Q was materially false and misleading because Vanda was informed by the FDA on the 5/15/18 Call that the FDA would impose a clinical hold on an extension study of the 2301 Study if Vanda did not complete the required non-rodent toxicity study to ensure that tradipitant is safe to use in humans. By falsely claiming that "no material changes" to Vanda's risk factors had occurred during 2Q18 with respect to complying with FDA regulations, this statement was materially false and misleading to investors because Vanda knew all along that it would not conduct the required non-rodent study and that this refusal would trigger a clinical trial hold.

393. On November 7, 2018, the Company issued a press release, which was also filed on Form 8-K, that provided Vanda's 3Q18 financial results and performance to analysts and investors (the "11/718 Form 8-K"). The 11/7/18 Form 8-K stated:

> *Enrollment in the clinical study of tradipitant in gastroparesis is complete. Results are expected by the end of 2018.*

394. The statements referenced above in ¶393 were materially false and misleading for the reasons set forth in ¶385.

395. During the 11/7/18 Call, defendant Polymeropoulos stated:

> Tradipitant, the most exciting clinical milestone for Vanda, is coming up in the next few weeks. *And it will come from the top line results of our first Phase II study of tradipitant in gastroparesis*. Gastroparesis is a common and poorly treated disorder with a significant unmet medical need affecting about 6 million people in the U.S. alone. *Our Phase II study, of which we'll report the results next month, is a 150-patient, 2-arm, double-blind tradipitant versus placebo 85-milligram twice a day of tradipitant to evaluate the ability of the drug to improve symptoms of gastroparesis over a period of 4 weeks.*

396. The statements referenced above in ¶395 that "it will come from the top line results of our first Phase II study of tradipitant in gastroparesis" and "[o]ur Phase II study . . ." were materially false and misleading for the reasons set forth in ¶385.

397. The 3Q18 Form 10-Q stated:

> *Enrollment in the clinical study of tradipitant in gastroparesis is complete. Results are expected by the end of 2018.*

398. The statements referenced above in ¶397 were materially false and misleading for the reasons set forth in ¶385.

399. The 3Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> *There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.*

400. The statement referenced above in ¶399 was materially false and misleading for the reasons set forth in ¶392.

401. The 12/3/18 Form 8-K stated:

> *Vanda expects to meet with regulatory authorities in the near future to further define and confirm the path towards registration of tradipitant in the treatment of patients with gastroparesis.*

402. By speaking about Vanda's interactions with the FDA to discuss future clinical trials for tradipitant related to gastroparesis, the Individual Defendants had a duty to speak fully and truthfully. Because the Individual Defendants failed to disclose that Vanda was informed by the FDA on the 5/15/18 Call that the Company's refusal to conduct a nine-month non-rodent toxicity study to ensure that tradipitant is safe in humans meant that the FDA would impose a clinical hold on any tradipitant trial over three months in duration, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The

Individual Defendants' failure to adequately disclose an accurate portrayal of the status of tradipitant clinical trials during the Relevant Period rendered this statement materially false and misleading.

403. On December 3, 2018, defendants Polymeropoulos and Kelly also hosted a conference call with analysts and investors to announce positive results from the 2301 Study (the "12/3/18 Call"). During the 12/3/18 Call, defendant Polymeropoulos stated:

> Finally, we believe that if these robust efficacy results with a well-tolerated chronic treatment safety profile are further confirmed in future studies, tradipitant has the potential to become a first-line pharmacological option in the treatment of patients with gastroparesis and the first such agent in 40 years. The detailed results of the study are expected to be presented in our cabin meetings and peer-reviewed publications. *We will also be meeting with regulatory authorities in the near future to further define and confirm the path towards registration of tradipitant in the treatment of patients with gastroparesis*.
>
> * * *
>
> Pete, certainly, we want to continue to evaluate the effectiveness of the drug in the broad population of gastroparetic patients. However, I would say while we have some very good ideas of potential designs and population of patients, we need to spend a little more time understanding these study results, *but also sit down with key opinion leaders, investigators, and certainly, the Food and Drug Administration to find out the fastest to market.* And the reason for that is we recognize that what tradipitant has shown in this Phase II study, can be an extremely usefultherapeutic tool for patients.
>
> * * *
>
> Analyst (Esther Rajavelu, Oppenheimer): "And then my last question. Are you -- do you anticipate having to do a long-term safety study on -- in the gastroparesis population given the chronic nature of the condition and the treatment?
>
> Defendant Polymeropoulos: "Absolutely, I would be very appropriate to do so. *And in fact, we have a 12-month protocol, which we'll be implementing shortly*.

404. The statements referenced above in ¶403 that "[w]e will also be meeting with regulatory authorities in the near future . . ." and "sit down with . . . the Food and Drug

Administration to find out the fastest to market" were materially false and misleading for the reasons set forth in ¶402.

405. The statement referenced above in ¶403 that "we have a 12-month protocol, which we'll be implementing shortly" was materially false and misleading when made because it misrepresented the following facts, which the Individual Defendants knew, or recklessly disregarded:

a) Vanda could not implement a 12-month protocol for tradipitant shortly because the FDA told Vanda on the 5/15/18 Call that the Company had to first conduct a nine-month non-rodent study to ensure that tradipitant is safe to use in humans;

b) Vanda was unwilling at all relevant times to conduct the required nine-months safety study; and

c) Vanda intended to sue the FDA if the FDA placed the expected clinical trial holds on any tradipitant studies over three months in length.

DEFENDANTS DUGAN, MILANO, BATE, COLA, POLYMEROPOULOS, AND WATKINS APPROVE TWO FALSE AND MISLEADING PROXY STATEMENTS IN ORDER TO PERPETUATE THE OFF-LABEL PROMOTION SCHEME, GET RE-ELECTED, AND INCREASE THEIR COMPENSATION

1. THE FALSE AND MISLEADING 2017 PROXY STATEMENT

406. On April 27, 2017, defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins, reviewed, approved, and caused the Company to file a Proxy Statement (the "2017 Proxy").

407. In the 2017 Proxy, the Board sought shareholder approval for the following proposals: (1) the re-election of defendants Dugan and Milano; (2) the amendment and restatement of the Company's 2016 Equity Incentive Plan to, among other things, increase the aggregate number of shares authorized for issuance under the 2016 Equity Incentive Plan; and (3) to approve on an advisory basis the named executive officer compensation.

408. With respect to Risk Management, the 2017 Proxy stated:

> Our Board oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our Company, our Board provides oversight to address the primary risks associated with those operations and corporate functions. In addition, our Board reviews the risks associated with the Company's business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.
>
> Each committee of our Board also oversees the management of the Company's risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer reports to the Audit Committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its oversight role, our Audit Committee meets privately with representatives from our independent registered public accounting firm and our Chief Financial Officer.
>
> The oversight of risk within the Company is an evolving process requiring the Company to continually look for opportunities to further embed systematic enterprise risk management into ongoing business processes within the Company. The Board encourages management to continue to drive this evolution.

409. With respect to defendant Dugan, and in support of his re-election to the Board, the 2017 Annual Proxy stated: "We believe that Mr. Dugan's qualifications to sit on the Board include his more than 25 years as a Partner with Ernst & Young, LLP, his long history with the Company, his status as a financial expert under The Sarbanes-Oxley Act of 2002 and his experience on other public company boards."

410. With respect to defendant Milano, and in support of his re-election to the Board, the 2017 Annual Proxy stated: "We believe that Mr. Milano's qualifications to sit on the Board include his executive experience in the pharmaceutical industry, his knowledge of finance and accounting, and his experience on other public company boards."

411. The 2017 Annual Proxy also stated that the Company had a Code of Conduct:

Code of Ethics and Business Conduct

> The Company has adopted the Vanda Pharmaceuticals Inc. Code of Ethics and Business Conduct that applies to all directors, officers and employees. This code is available in the Corporate Governance section of our corporate website at www.vandapharma.com. If we make any substantive amendments to this code or grant any waiver from a provision of the code to any applicable executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

412. The 2017 Annual Proxy further stated the following regarding the responsibilities of the Audit Committee:

Audit Committee

> The Audit Committee of the Board oversees the quality and integrity of the Company's financial statements and other financial information provided to the Company's stockholders, the retention and performance of the Company's independent accountants, the effectiveness of the Company's internal controls and disclosure controls, and the Company's compliance with ethics policies and SEC and related regulatory requirements. For these purposes, the Audit Committee, among other duties and powers, (1) approves audit fees for, and selects and reviews the performance of, the Company's independent accountants, (2) reviews reports prepared by management, and attested by the Company's independent accountants with respect to the financial statements contained therein, assessing the adequacy and effectiveness of the Company's internal controls and procedures, prior to the inclusion of such reports in the Company's periodic filings as required under the rules of the SEC, (3) reviews the Company's annual and quarterly reports, and associated consolidated financial statements, with management and the independent accountants prior to the first public release of the Company's financial results for such year or quarter, (4) reviews with external counsel any legal matters that could have a significant impact on the Company's financial statements, and (5) establishes and maintains procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls and auditing matters. Our Audit Committee charter can be found in the corporate governance section of our corporate website at www.vandapharma.com. Three directors comprised the Audit Committee as of December 31, 2016: Mr. Dugan (the Chairman of the Audit Committee), Mr. Cola and Mr. Milano. The Audit Committee met six times during 2016.

413. As detailed herein, defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins, had knowledge of Vanda's unlawful off-label promotion scheme which were fundamentally predicated on knowingly violating regulatory requirements and FDA regulations

and which put the Company at material risk, and yet wrongfully failed to disclose this information to shareholders.

414. Accordingly, the 2017 Annual Proxy both incorrectly claimed and represented to reasonable investors when they were voting that: (i) the Board was engaged in proper and active risk oversight of the Company; (ii) the Board was in compliance with the Code of Ethics and Business Conduct; (iii) the Audit Committee exercised appropriate oversight of the Company's financial statements and reporting, monitored compliance with securities and financial regulations, reviewed disclosure controls so that the Company was compliant with laws and regulations, and oversaw financial risks; and (iv) as a result, the Board, including defendants Dugan (who was Chairman of the Audit Committee) and Milano who were each up for reelection, were in compliance with their duties and exercised appropriate oversight over Vanda's operations, risk management, controls, and public disclosures.

415. In reality, the Board, and its Audit Committee did not exercise active and appropriate oversight over the Company's operations, compliance, risk management, controls, and public disclosures as described in the 2017 Annual Proxy. Instead, as described herein, they made or allowed to be made improper statements in Vanda's press releases, public filings, and other public statements relating to the Company's compliance; they failed to appropriately implement functioning risk management processes designed to address significant risks to the Company such as risks associated with the Company's off-label promotion scheme; and they utterly failed to ensure compliance with applicable securities laws through implementation of functioning disclosure controls and procedures. Accordingly, the defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins were negligent in including these misleading statements in the 2017 Annual Proxy Statement.

416. The 2017 Annual Proxy harmed Vanda by interfering with the free and informed exercise of the Company's stockholders' right to vote for directors. As a result of the misleading statements in these proxies, Vanda's stockholders voted via an uninformed stockholder vote to reelect defendants Milano and Dugan.

417. In addition, the 2017 Proxy outlined how executive compensation was based on a pay-for-performance basis:

Compensation Program Philosophy

> Our Compensation Committee has determined that our executive compensation program generally targets the executive team's base salaries and total target cash compensation to the 50th percentile of similarly situated named executive officers at our peer group companies and the executive team's total equity compensation to roughly the 66th percentile of similarly situated named executive officers at our peer group companies. Our Compensation Committee may exceed the target percentiles for certain of our named executive officers based on extraordinary performance. Our Compensation Committee believes that these targets are aligned with competitive market practices, thus enabling us to recruit and retain the talent needed to deliver on our business strategy. In addition, this competitive positioning allows for alignment with a ***pay-for-performance philosophy*** with premium levels of cash compensation only awarded for performance that exceeds target levels for pre-determined business and individual goals and equity awards that are a key component of the total rewards package. Our 2016 executive compensation program advances this philosophy.

418. Moreover, the Vanda 2016 Equity Incentive Plan itself was depicted as rewarding its participants, including the Individual Defendants, on the basis of performance:

> *Performance Awards*. The 2016 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered named executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.
>
> A performance stock award is a stock award that is payable (including that may be granted, may vest, or may be exercised) contingent upon the achievement

of pre-determined performance goals during a performance period. A performance stock award may require the completion of a specified period of continuous service. The length of any performance period, the performance goals to be achieved during the performance period, and the measure of whether and to what degree such performance goals have been attained will generally be determined by our compensation committee, except that the plan administrator also may make any such determinations to the extent that the award is not intended to comply with Section 162(m) of the Code. In addition, to the extent permitted by applicable law and the performance stock award agreement, the plan administrator may determine that cash may be used in payment of performance stock awards.

A performance cash award is a cash award that is payable contingent upon the achievement of pre-determined performance goals during a performance period. A performance cash award may require the completion of a specified period of continuous service. The length of any performance period, the performance goals to be achieved during the performance period, and the measure of whether and to what degree such performance goals have been attained will generally be determined by our compensation committee, except that the plan administrator also may make any such determinations to the extent that the award is not intended to comply with Section 162(m) of the Code. The plan administrator may specify the form of payment of performance cash awards, which may be cash or other property, or may provide for a participant to have the option for his or her performance cash award, or such portion thereof as the plan administrator may specify, to be paid in whole or in part in cash or other property.

In granting a performance award intended to qualify as "performance-based compensation" under Section 162(m) of the Code, our compensation committee will set a period of time, or a performance period, over which the attainment of one or more goals, or performance goals, will be measured. Within the time period prescribed by Section 162(m) of the Code (no later than the earlier of the 90th day of a performance period and the date on which 25% of the performance period has elapsed, and in any event at a time when the achievement of the performance goals remains substantially uncertain), our compensation committee will establish the performance goals, based upon one or more criteria, or performance criteria, enumerated in the 2016 Plan and described below. As soon as administratively practicable following the end of the performance period, our compensation committee will certify in writing whether the performance goals have been satisfied.

Performance goals under the 2016 Plan are based on any one or more of the following performance criteria: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization, or EBITDA; (4) growth of earnings before interest and taxes; (5) EBITDA margin, adjusted EBITDA margin, or adjusted EBITDA; (6) total stockholder return; (7) return on equity or average stockholder's equity; (8) return on assets, net assets, investment, or capital

> employed; (9) stock price; (10) margin (including gross margin); (11) income (before or after taxes); (12) net income or operating income; (13) operating income after taxes; (14) pre-tax profit or after-tax profit; (15) operating cash flow; (16) revenue or sales (including revenue or sales targets); (17) increases in revenue or product revenue; (18) expenses and costs (including expenses and cost reduction goals); (19) improvement in or attainment of working capital levels or expense levels; (20) economic value added (or an equivalent metric); (21) market share; (22) cash flow; (23) cash flow per share; (24) earnings per share; (25) share price or share price performance; (26) debt reduction; (27) implementation or completion of projects or processes; (28) customer satisfaction; (29) number of customers; (30) stockholders' equity; (31) return on stockholders' equity; (32) capital expenditures; (33) debt levels; (34) operating profit or net operating profit; (35) workforce diversity; (36) growth of net income or operating income; (37) billings; (38) days sales outstanding; and (39) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the plan administrator.
>
> Performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Under the 2016 Plan, unless specified otherwise by the board of directors (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the performance goals are established, the board of directors will appropriately make adjustments in the method of calculating the attainment of performance goals for a performance period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated performance goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; and (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles. In addition, our compensation committee (or, if not required for compliance with Section 162(m) of the Code, the plan administrator) retains the discretion to reduce or eliminate the compensation or economic benefit due upon the attainment of any performance goals and to define the manner of calculating the performance criteria it selects to use for a performance period.

419. The 2017 Annual Proxy harmed Vanda by preventing the Company's shareholders from making an informed decision as to whether to approve executive compensation on an advisory basis and whether to approve the amendment and restatement of the Company's 2016 Equity Incentive Plan, which provided additional shares to the plan for additional compensation to the Company's officers and directors, including the Individual Defendants. Vanda stockholders

would never have voted to approve executive compensation on an advisory basis and to amend and restate the Company's 2016 Equity Incentive Plan had they known the Individual Defendants were knowingly aware of or recklessly disregarded the off-label promotion scheme for Fanapt and Hetlioz and that Vanda refused to conduct a safety trial for tradipitant that was needed for it to ultimately received FDA approval. The Individual Defendants' actions were contrary to the Company's stated compensation practices in the 2017 Annual Proxy and sought to award compensation not based on performance as represented, but rather on false and misleading statements that depicted a rosy picture of the Company's financial condition.

2. THE FALSE AND MISLEADING 2018 ANNUAL PROXY STATEMENT

420. On April 27, 2018, defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins, reviewed, approved, and caused the Company to file a Proxy Statement (the "2018 Proxy" or "2018 Annual Proxy") (the "2017 Proxy together with the "2018 Proxy" are referred to herein as the "Proxy Statements").

421. In the 2018 Annual Proxy, the Board sought shareholder approval for the following proposals: (1) the re-election of defendant Polymeropoulos; (2) approve an amendment and restatement of the Company's amended and restated 2016 Equity Incentive Plan ("2016 Plan") to, among other things, increase the aggregate number of shares authorized for issuance under the 2016 Plan; and (3) to approve on an advisory basis the named executive officer compensation.

422. With respect to Risk Management, the 2018 Proxy stated:

> **Risk Oversight**
>
> Our Board oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. The general categories of risk overseen by the our Board include, without limitation, operational risk, commercial risk, clinical trial risk, capital risk, credit risk, earnings risk, liquidity risk, market risk, price risk, legal/compliance risk, cyber risk and reputational risk. Our Board performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our

> Company, our Board provides oversight to address the primary risks associated with those operations and corporate functions. In addition, our Board reviews the risks associated with the Company's business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.
>
> Each committee of our Board also oversees the management of the Company's risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer reports to the Audit Committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its oversight role, our Audit Committee meets privately with representatives from our independent registered public accounting firm and our Chief Financial Officer.
>
> The oversight of risk within the Company is an evolving process requiring the Company to continually look for opportunities to further embed systematic enterprise risk management into ongoing business processes within the Company. The Board encourages management to continue to drive this evolution.

423. With respect to defendant Polymeropoulos, and in support of his re-election to the Board, the 2017 Annual Proxy stated:

> Mihael H. Polymeropoulos, M.D. co-founded Vanda and has served as President, Chief Executive Officer and a Director since May 2003. Prior to joining Vanda, Dr. Polymeropoulos was Vice President and Head of the Pharmacogenetics Department at Novartis AG from 1998 to 2003. Prior to his tenure at Novartis, he served as Chief of the Gene Mapping Section, Laboratory of Genetic Disease Research, National Human Genome Research Institute, from 1992 to 1998. Dr. Polymeropoulos is the co-founder of the Integrated Molecular Analysis of Genome Expression Consortium. Dr. Polymeropoulos holds a degree in Medicine from the University of Patras. We believe that Dr. Polymeropoulos' qualifications to sit on the Board include his executive experience at Novartis, his expertise in the fields of psychiatry and pharmacogenetics, his extensive knowledge of central nervous system disorders and his long history with the Company.

424. The 2018 Proxy also stated that the Company had a Code of Conduct:

> **Code of Ethics and Business Conduct**
>
> The Company has adopted the Vanda Pharmaceuticals Inc. Code of Ethics and Business Conduct that applies to all directors, officers and employees. This code is available in the Corporate Governance section of our corporate website at www.vandapharma.com. If we make any substantive amendments to this code or grant any waiver from a provision of the code to any applicable executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

425. The 2018 Annual Proxy further stated the following regarding the responsibilities of the Audit Committee:

> The Audit Committee of the Board oversees the quality and integrity of the Company's financial statements and other financial information provided to the Company's stockholders, the retention and performance of the Company's independent accountants, the effectiveness of the Company's internal controls and disclosure controls, and the Company's compliance with ethics policies and SEC and related regulatory requirements. For these purposes, the Audit Committee, among other duties and powers, (1) approves audit fees for, and selects and reviews the performance of, the Company's independent accountants, (2) reviews reports prepared by management, and attested by the Company's independent accountants with respect to the financial statements contained therein, assessing the adequacy and effectiveness of the Company's internal controls and procedures, prior to the inclusion of such reports in the Company's periodic filings as required under the rules of the SEC, (3) reviews the Company's annual and quarterly reports, and associated consolidated financial statements, with management and the independent accountants prior to the first public release of the Company's financial results for such year or quarter, (4) reviews with external counsel any legal matters that could have a significant impact on the Company's financial statements, and (5) establishes and maintains procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls and auditing matters. Our Audit Committee charter can be found in the Corporate Governance section of our corporate website at www.vandapharma.com. Three directors comprised the Audit Committee as of December 31, 2017: Mr. Dugan (the Chairman of the Audit Committee), Mr. Cola and Mr. Milano. The Audit Committee met nine times during 2017.

426. As detailed herein, defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins, had knowledge of Vanda's unlawful off-label promotion scheme which were fundamentally predicated on knowingly violating regulatory requirements and FDA regulations and which put the Company at material risk, and yet wrongfully failed to disclose this information to shareholders.

427. Accordingly, the 2018 Annual Proxy both incorrectly claimed and represented to reasonable investors when they were voting that: (i) the Board was engaged in proper and active risk oversight of the Company; (ii) the Board was in compliance with the Code of Ethics and Business Conduct; (iii) the Audit Committee exercised appropriate oversight of the Company's

financial statements and reporting, monitored compliance with securities and financial regulations, reviewed disclosure controls so that the Company was compliant with laws and regulations, and oversaw financial risks; and (iv) as a result, the Board, including defendant Polymeropoulos, who was up for reelection, were in compliance with their duties and exercised appropriate oversight over Vanda's operations, risk management, controls, and public disclosures.

428. In reality, the Board, and its Audit Committee did not exercise active and appropriate oversight over the Company's operations, compliance, risk management, controls, and public disclosures as described in the 2018 Annual Proxy. Instead, as described herein, they made or allowed to be made improper statements in Vanda's press releases, public filings, and other public statements relating to the Company's compliance; they failed to appropriately implement functioning risk management processes designed to address significant risks to the Company such as risks associated with the Company's off-label promotion scheme; and they utterly failed to ensure compliance with applicable securities laws through implementation of functioning disclosure controls and procedures. Accordingly, defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins were negligent in including these misleading statements in the 2018 Annual Proxy Statement.

429. The 2018 Annual Proxy harmed Vanda by interfering with the free and informed exercise of the Company's stockholders' right to vote for directors. As a result of the misleading statements in these proxies, Vanda's stockholders voted via an uninformed stockholder vote to reelect defendant Polymeropoulos.

430. In addition, the 2018 Proxy outlined how executive compensation was based on a pay-for-performance basis:

Compensation Program Philosophy

> Our Compensation Committee has determined that our executive compensation program generally targets the executive team's base salaries and total target cash compensation to the 50th percentile of similarly situated named executive officers at our peer group companies and the executive team's total equity compensation to approximately the 66th percentile of similarly situated named executive officers at our peer group companies, with the goal of achieving a total compensation mix targeting the 50th percentile of peer group companies over time. The components and target percentiles for our named executive offices is evaluated on a yearly basis by our Compensation Committee. Our Compensation Committee has the flexibility to adjust individual percentile positioning when making individual pay decisions for our named executive officers based on performance. Our Compensation Committee believes that these targets are aligned with competitive market practices, thus enabling us to recruit and retain the talent necessary for the Company to deliver on our business strategy. In addition, this competitive positioning allows for alignment with a ***pay-for-performance philosophy*** with premium levels of cash compensation only awarded for performance that exceeds target levels for pre-determined business and individual goals and equity awards that are a key component of the total rewards package. Our 2017 executive compensation program advances this philosophy.

431. Moreover, Vanda's 2016 Plan itself was depicted as rewarding its participants, including the Individual Defendants, on the basis of performance:

> *Performance Awards.* The 2016 Plan permits the grant of performance-based stock and cash awards that may have qualified as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered named executive officer imposed by Section 162(m) prior to the enactment of the 2017 Tax Cuts and Jobs Act. To help assure that the compensation attributable to performance-based awards would have qualified, our compensation committee could have structured awards prior to November 2, 2017 so that stock or cash would have been issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.
>
> A performance stock award is a stock award that is payable (including that may be granted, may vest or may be exercised) contingent upon the achievement of pre-determined performance goals during a performance period. A performance stock award may require the completion of a specified period of continuous service. Performance stock awards may be subject to one or more minimum performance requirements, and will not commence vesting until the grantee has completed at least one year of performance and/or service. The length of any performance period, the performance goals to be achieved during the performance period, and the measure of whether and to what degree such performance goals have been attained will generally be determined by our compensation committee, except that the plan administrator also may make any such determinations to the extent that the

award is not intended to comply with Section 162(m) of the Code. In addition, to the extent permitted by applicable law and the performance stock award agreement, the plan administrator may determine that cash may be used in payment of performance stock awards.

A performance cash award is a cash award that is payable contingent upon the achievement of pre-determined performance goals during a performance period. A performance cash award may require the completion of a specified period of continuous service. The length of any performance period, the performance goals to be achieved during the performance period and the measure of whether and to what degree such performance goals have been attained will generally be determined by our compensation committee, except that the plan administrator also may make any such determinations to the extent that the award is not intended to comply with Section 162(m) of the Code. The plan administrator may specify the form of payment of performance cash awards, which may be cash or other property, or may provide for a participant to have the option for his or her performance cash award, or such portion thereof as the plan administrator may specify, to be paid in whole or in part in cash or other property.

In granting a performance award intended to qualify as "performance-based compensation" under Section 162(m) of the Code, our compensation committee will set a period of time, or a performance period, over which the attainment of one or more goals, or performance goals, will be measured. Within the time period prescribed by Section 162(m) of the Code (no later than the earlier of the 90th day of a performance period and the date on which 25% of the performance period has elapsed, and in any event at a time when the achievement of the performance goals remains substantially uncertain), our compensation committee will establish the performance goals, based upon one or more criteria, or performance criteria, enumerated in the 2016 Plan and described below. As soon as administratively practicable following the end of the performance period, our compensation committee will certify in writing whether the performance goals have been satisfied.

Performance goals under the 2016 Plan are based on any one or more of the following performance criteria: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization, or EBITDA; (4) growth of earnings before interest and taxes; (5) EBITDA margin, adjusted EBITDA margin, or adjusted EBITDA; (6) total stockholder return; (7) return on equity or average stockholder's equity; (8) return on assets, net assets, investment, or capital employed; (9) stock price; (10) margin (including gross margin); (11) income (before or after taxes); (12) net income or operating income; (13) operating income after taxes; (14) pre-tax profit or after-tax profit; (15) operating cash flow; (16) revenue or sales (including revenue or sales targets); (17) increases in revenue or product revenue; (18) expenses and costs (including expenses and cost reduction goals); (19) improvement in or attainment of working capital levels or expense

> levels; (20) economic value added (or an equivalent metric); (21) market share; (22) cash flow; (23) cash flow per share; (24) earnings per share; (25) share price or share price performance; (26) debt reduction; (27) implementation or completion of projects or processes; (28) customer satisfaction; (29) number of customers; (30) stockholders' equity; (31) return on stockholders' equity; (32) capital expenditures; (33) debt levels; (34) operating profit or net operating profit; (35) workforce diversity; (36) growth of net income or operating income; (37) billings; (38) days sales outstanding; and (39) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the plan administrator.
>
> Performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Under the 2016 Plan, unless specified otherwise by the board of directors (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the performance goals are established, the board of directors will appropriately make adjustments in the method of calculating the attainment of performance goals for a performance period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated performance goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; and (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles. In addition, our compensation committee (or, if not required for compliance with Section 162(m) of the Code, the plan administrator) retains the discretion to reduce or eliminate the compensation or economic benefit due upon the attainment of any performance goals and to define the manner of calculating the performance criteria it selects to use for a performance period.

432. The 2018 Annual Proxy harmed Vanda by preventing the Company's shareholders from making an informed decision as to whether to approve executive compensation on an advisory basis and whether to approve the amendment and restatement of the Company's 2016 Plan, which provided additional shares to the plan for additional compensation to the Company's officers and directors, including the Individual Defendants. Vanda stockholders would never have voted to approve executive compensation on an advisory basis and to amend and restate the Company's 2016 Plan had they known the Individual Defendants were knowingly aware of, or recklessly disregarded, the off-label promotion scheme for Fanapt and Hetlioz and that Vanda

refused to conduct a safety trial for tradipitant that was needed for it to ultimately received FDA approval. The Individual Defendants' actions were contrary to the Company's stated compensation practices in the 2018 Annual Proxy and sought to award compensation not based on performance as represented, but rather on false and misleading statements that depicted a rosy picture of the Company's financial condition.

THE TRUTH EMERGES

433. On February 5, 2019, after the close of the trading day, Vanda issued a press release and announced, among other things, that the Company had initiated the FDA Litigation because the FDA had issued clinical trial holds for tradipitant studies. The next day, February 6, Vanda filed the February 5 press release with the SEC on Form 8-K.

434. In response to the aftermarket revelations on February 5, 2019, the trading price of Vanda's common stock declined from a closing price of $25.06 per share on February 5, to a closing price of $20.06 per share on February 6 – a decline of $5.00 per share, or 19.95%.

435. Then, during the trading day on February 11, 2019, Aurelius Report, titled "Vanda: In the Land of the Blind, The One-Eyed Man is King," was issued that, among other things, publicly disclosed for the first time Vanda's off-label promotion scheme for Fanapt and Hetlioz.

436. In response to the revelations on February 11, 2019, the trading price of Vanda's common stock declined from an opening price of $19.05 per share on February 11 to a closing price of $18.00 per share on February 11 – a decline of $1.05 per share, or 5.51%.

DAMAGES TO VANDA

437. As a result of the Individual Defendants' wrongful conduct, Vanda disseminated false and misleading statements and omitted material information to make such statements not false and misleading when made. The improper statements have devastated Vanda's credibility.

Vanda has been, and will continue to be, severely damaged and injured by the Individual Defendants' misconduct.

438. The Individual Defendants' improper course of conduct has also subjected the Company to costs and expenses damages in connection with the Securities Class Action, the FDA Litigation, and the Qui Tam Litigation.

439. Moreover, these actions have irreparably damaged Vanda' corporate image and goodwill. For at least the foreseeable future, Vanda will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Vanda' ability to raise equity capital or debt on favorable terms in the future is now impaired.

440. Further, as a direct and proximate cause of the Individual Defendants' actions, Vanda has expended significant money from the costs incurred from the substantial compensation and benefits paid to defendants Polymeropoulos, Kelly, and Reverberi who are liable for the wrongdoing alleged herein.

PLAINTIFF'S DEMAND AND DERIVATIVE ALLEGATIONS

441. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

442. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress the Individual Defendants' breaches of fiduciary duties.

443. Plaintiff is an owner of Vanda common stock and was an owner of Vanda common stock at all times relevant hereto.

444. Plaintiff will adequately and fairly represent the interests of the Company and its stockholders in enforcing and prosecuting its rights.

445. As a result of the facts set forth herein, Plaintiff has not made any demand on the Vanda Board to institute this action against the Individual Defendants. Such a demand would be a futile and useless act because the Board is incapable of making an independent and disinterested decision to institute and vigorously prosecute this action.

446. Vanda's current Board consists of defendants Watkins, Polymeropoulos, Cola, Dugan (collectively, the "Director Defendants"), and non-defendant Phaedra Chrousos ("Chrousos"). The Director Defendants, which constitute a majority of the Board, are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action.

DEMAND IS EXCUSED AS TO DEFENDANT POLYMEROPOULOS BECAUSE HE IS INTERESTED AND LACKS INDEPENDENCE

447. Defendant Polymeropoulos is not an independent director because his principal professional occupation is his employment with Vanda. Polymeropoulos co-founded Vanda and has served as its President, Chief Executive Officer since May 2003, and has received and continues to receive substantial monetary compensation and other benefits. According to the 2019 Proxy, in 2017 and 2018, Polymeropoulos received total compensation of $3,797,395 and $4,284,676, respectively. These amounts are material to him.

448. Accordingly, defendant Polymeropoulos lacks independence from defendants Watkins, Cola, Dugan and Chrousos due to his interest in maintaining his executive position and the compensation that flows from it. This lack of independence renders defendant Polymeropoulos incapable of impartially considering a demand to commence and vigorously prosecute this action.

449. Moreover, defendant Polymeropoulos has actual knowledge of the alleged misconduct happened in the Company, as described above. Defendant Polymeropoulos is also incapable of considering a demand to commence and vigorously prosecute this action because he

faces additional substantial likelihood of liability as he is a named defendant in the Securities Class Action.

450. Finally, Vanda has conceded in its SEC filings that defendant Polymeropoulos is not an independent director. According to the Company, he cannot be deemed independent under Nasdaq listing standards.

DEMAND IS EXCUSED AS TO THE DIRECTOR DEFENDANTS BECAUSE THEY FACE A SUBSTANTIAL LIKELIHOOD OF LIABILITY

451. The Director Defendants breached their fiduciary duties of loyalty and good faith by making or allowing to be made improper statements in Vanda's press releases, public filings, and other public statements relating to the Company's off-label promotion scheme for Fanapt and Hetlioz and that Vanda refused to conduct a safety trial for tradipitant that was needed for it to ultimately received FDA approval. In making or allowing these improper statements, the Director Defendants breached their fiduciary duties. The Director Defendants were directors throughout the time of the false and misleading statements, and as such had a fiduciary duty to ensure that the Company's SEC filings, press releases, and other public statements and presentations on behalf of the Company concerning its business, compliance with rules and regulations, operations, prospects, internal controls, and financial statements were accurate. Accordingly, the Director Defendants face a substantial likelihood of liability for their breach of fiduciary duties, making any demand upon them futile.

452. Any suit by the current directors of Vanda to remedy these wrongs would also expose defendant Polymeropoulos (and defendants Kelly, Reverberi, and Nominal Defendant Vanda) to liability for violations of the federal securities laws in the pending Securities Class Action, and would result in civil actions being filed against one or more of the other Individual Defendants. The Securities Class Action alleges violations of sections 10(b) and 20(a) of the

Exchange Act. If the Board elects for the Company to press forward with its right of action against defendant Polymeropoulos and others in this action, then Vanda's efforts would compromise its defense of the Securities Class Action.

453. Moreover, the Director Defendants as directors owed a duty to, in good faith and with due diligence, exercise reasonable inquiry, oversight, and supervision to ensure that the Company's internal controls were sufficiently robust and effective (and were being implemented effectively), and to ensure that the Board's duties were being discharged in good faith and with the required diligence and due care. Instead, they knowingly and consciously reviewed, authorized and/or caused the publication of the materially false and misleading statements discussed above.

454. Finally, the Director Defendants' conscious and knowing authorization of false and misleading statements, failure to timely correct such statements, failure to take necessary and appropriate steps to ensure that the Company's internal controls were sufficiently robust and effective (and were being implemented effectively), failure to ensure that the Company was in compliance with all rules and regulations, particularly FDA regulations, failure to take necessary and appropriate steps to ensure that the Board's duties were being discharged in good faith, and with the required diligence constitute breaches of the fiduciary duties of loyalty and good faith, for which the Director Defendants face a substantial likelihood of liability. If the Director Defendants were to bring a suit on behalf of Vanda to recover damages sustained as a result of this misconduct, they would expose themselves to significant liability. This is something they will not do. For this reason, demand is futile as to the Director Defendants.

DEMAND IS EXCUSED AS TO DEFENDANTS DUGAN AND COLA BECAUSE AS MEMBERS OF THE AUDIT COMMITTEE THEY FACE A SUBSTANTIAL LIKELIHOOD OF LIABILITY

455. Defendants Dugan and Cola oversee Vanda's compliance with legal and regulatory requirements, including public disclosure controls and procedures, as well as its risk assessment

and management, and internal control functions. Thus, the Audit Committee Defendants were responsible for knowingly or recklessly allowing the improper statements detailed herein. The Audit Committee Defendants breached their fiduciary duty of loyalty and good faith by approving or otherwise allowing the improper statements, and therefore failing to properly oversee Vanda's compliance with legal and regulatory requirements, including FDA regulations, and the Company's disclosure controls. For these reasons, defendants Dugan and Cola face a substantial likelihood of liability for their breach of fiduciary duties, making any demand upon them futile.

DEFENDANT COLA IS UNABLE TO INDEPENDENTLY CONSIDER A DEMAND DUE TO HIS BUSINESS AFFILIATIONS

456. Defendant Cola is incapable of impartially considering a demand to commence and vigorously prosecute this action due to his long-standing, overlapping business relationships. In particular, Cola served as President of Shire plc's ("Shire") Specialty Pharmaceuticals business from 2007 until April 2012. Mr. Cola joined Shire in July 2005 as Executive Vice President for Global Therapeutic Business Units and Portfolio Management prior to being named President of the Specialty Pharmaceuticals business.

457. Defendant Reverberi served as Senior Vice President, International Specialty Pharma at Shire. In addition to his International Specialty Pharma responsibilities, from 2009 to 2013, Reverberi led Shire's Internal Medicine Global Business Unit. Prior to this position, he was General Manager, Italy at Shire. Accordingly, there is reasonable doubt that defendant Cola would vote to initiate litigation against defendant Reverberi due to their long-standing business relationships. Demand is therefore futile as to defendant Cola.

458. Defendant Milano served as Chairman, President, and Chief Executive Officer of ViroPharma, which was acquired by Shire Pharmaceuticals on January 2, 2014. Mr. Milano joined ViroPharma in 1996 and served as Vice President, Chief Financial Officer, and Treasurer from

1997 to 2006 prior to becoming Chief Executive Officer. Accordingly, there is reasonable doubt that defendant Milano would vote to initiate litigation against defendant Reverberi due to their long-standing business relationships. Demand is therefore futile as to defendant Milano.

COUNT I

VIOLATION OF SECTION 14(a) OF THE EXCHANGE ACT
(Against Defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins)

459. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

460. The section 14(a) Exchange Act claims alleged herein are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf of defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins. The section 14(a) Exchange Act claims alleged herein do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegation of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to the nonfraud claims.

461. Defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins negligently issued, caused to be issued, and participated in the issuance of materially misleading written statements to stockholders, which were contained in the Proxy Statements. In the Proxy Statements, the Board solicited stockholder votes to reelect defendants Dugan and Milano in the 2017 Proxy and defendant Polymeropoulos in the 2018 Proxy, to the Board.

462. The Proxy Statements both incorrectly claimed and represented to reasonable investors when they were voting that: (i) the Board was engaged in proper and active risk oversight of the Company; (ii) the Board was in compliance with the Code of Ethics and Business Conduct; (iii) the Audit Committee exercised appropriate oversight of the Company's financial statements and reporting, monitored compliance with securities and financial regulations, reviewed disclosure

controls so that the Company was compliant with laws and regulations, and oversaw financial risks; and (iv) as a result, the Board, including defendants Dugan and Milano who were each up for reelection in the 2017 Proxy and defendant Polymeropoulos who was up for relection in the 2018 Proxy, were in compliance with their duties and exercised appropriate oversight over Vanda's operations, risk management, controls, and public disclosures.

463. In addition, the Proxy Statements sought shareholder approval of amendments to and restatement of Vanda's 2016 Equity Incentive Plan. The Proxy Statements incorrectly claimed and led reasonable investors to believe that compensation at Vanda, including incentive awards under 2016 Equity Incentive Plan, was based on performance. These statements were false and misleading given the purported performance of the Company and the Individual Defendants was a mirage.

464. By reason of the conduct alleged herein, defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins violated section 14(a) of the Exchange Act. As a direct and proximate result of these defendants' wrongful conduct, Vanda misled and/or deceived its stockholders by making misleading statements that were an essential link in stockholders heeding Vanda's recommendation to reelect certain Board members and to approve and restate the 2016 Equity Incentive Plan.

465. Defendants Dugan, Milano, Bate, Cola, Polymeropoulos, and Watkins misled or deceived its stockholders by making misleading statements that were an essential link in the matters set forth in the Proxy Statements for which stockholder approval was sought.

466. The misleading information contained in the Proxy Statements was material to Vanda's stockholders in determining whether or not to approve the matters set forth in the Proxy Statements for which stockholder approval was sought.

467. Because of the false and misleading statements in the Proxy Statements, Vanda's shareholders voted to approve the matters set forth in the Proxy Statements for which stockholder approval was sought.

468. This claim is brought within the applicable statute of limitations.

COUNT II

BREACH OF FIDUCIARY DUTIES
(Against the Individual Defendants)

469. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

470. The Individual Defendants owed and owe Vanda fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Vanda the highest obligation of loyalty, good faith, due care, oversight, and candor.

471. All of the Individual Defendants violated and breached their fiduciary duties of loyalty, good faith, due care, oversight, and candor.

472. Each of the Individual Defendants consciously and deliberately breached their fiduciary duties of good faith, fair dealing, candor, loyalty, due care, reasonable inquiry, oversight, and supervision by being aware of the Company's off-label promotion scheme yet failing to address the regulatory violations in connection therewith.

473. Each of the Individual Defendants violated their fiduciary duties by consciously failing to prevent the Company from engaging in the unlawful acts complained of herein. The Individual Defendants intentionally, recklessly, or with gross negligence made improper statements in Vanda's press releases, public filings, and other public statements relating to the Company's off-label promotion scheme for Fanapt and Hetlioz and that Vanda refused to conduct a safety trial for tradipitant that was needed for it to ultimately received FDA approval.

474. The Individual Defendants were reckless or grossly negligent in disseminating the improper statements detailed herein. The Individual Defendants intentionally, recklessly, or with gross negligence made improper statements in Vanda's press releases, public filings, and other public statements. Accordingly, these defendants breached their duty of care and loyalty to the Company.

475. 157. The Audit Committee Defendants breached their fiduciary duty of loyalty by approving or otherwise allowing the improper statements, which they knew or were reckless in not knowing omitted material facts and contained material misstatements. The Audit Committee Defendants also completely and utterly failed in their duty of oversight and failed to properly oversee Vanda's (i) compliance with legal and regulatory requirements, (ii) public disclosure controls and procedures, (iii) risk assessment and management, and (iv) internal control functions.

476. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Vanda has sustained significant damages. Accordingly, these defendants are liable to the Company.

477. Plaintiff, on behalf of Vanda, has no adequate remedy at law.

COUNT III

FOR WASTE OF CORPORATE ASSETS (AGAINST THE INDIVIDUAL DEFENDANTS)

478. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

479. As a result of the Individual Defendants' wrongdoing Vanda is subject to the Securities Class Action, the FDA Litigation and the Qui Tam Litigation. The Individual Defendants have caused Vanda to waste its corporate assets by forcing the Company to expend

valuable resources in defending itself in the foregoing litigation, in addition to any ensuing costs from a potential settlement or adverse judgment.

480. In addition, as a result of the Individual Defendants' failure to implement adequate controls, defendants Polymeropoulos, Kelly and Reverberi were paid unwarranted compensation, bonuses, and other benefits compensation they did not earn and were not entitled to given the Company's actual performance. Vanda received no benefit from these improper payments.

481. As a result of their waste of corporate assets, the Individual Defendants are liable to the Company.

482. Plaintiff, on behalf of Vanda, has no adequate remedy at law.

COUNT IV

UNJUST ENRICHMENT
(Against the Defendants Polymeropoulos, Kelly and Reverberi)

483. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

484. By their wrongful acts and omissions, defendants Polymeropoulos, Kelly and Reverberi were unjustly enriched at the expense of and to the detriment of Vanda. Defendants Polymeropoulos, Kelly, and Reverberi were unjustly enriched as a result of the compensation they received while breaching fiduciary duties owed to Vanda. The Company received no benefit from these payments.

485. Plaintiff, as a stockholder and representative of Vanda, seek restitution from these defendants, and each of them, and seek an order of this Court disgorging all profits, benefits, and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

486. Plaintiff, on behalf of Vanda, has no adequate remedy at law

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Declaring that Plaintiff may maintain this derivative action on behalf of Vanda and that Plaintiff is a proper and adequate representative of the Company;

B. Awarding the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties and violations of the federal securities laws;

C. Ordering defendants Polymeropoulos, Kelly and Reverberi to return to Vanda all compensation and remuneration of whatever kind paid to them by Vanda during the time that they were in breach of the fiduciary duties they owed to Vanda;

D. Granting appropriate equitable relief to remedy Individual Defendants' breaches of fiduciary duties and other violations of law;

E. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees and costs and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury.

Dated: September 11, 2019

Respectfully Submitted,

/s/ Blake A. Bennett

COOCH AND TAYLOR, P.A.
Blake A. Bennett (#5133)
The Brandywine Building
1000 West Street, 10th Floor
Wilmington, DE 19801
Telephone: (302) 984-3800
Email: bbennett@coochtaylor.com

Attorney for Plaintiff

OF COUNSEL

BRAGAR EAGEL & SQUIRE, P.C.
W. Scott Holleman
Marion C. Passmore
Garam Choe
Alexandra B. Raymond
885 3rd Avenue, Suite 3040
New York, New York 10022
Telephone: (212) 355- 4648

HYNES & HERNANDEZ, LLC
Michael J. Hynes
Ligaya T. Hernandez
101 Lindenwood Drive, Suite 225
Malvern, Pennsylvania 19355
Telephone: (484) 875-3116

Attorneys for Plaintiff